Comparision of the Local Control Effects of Microballoon-Occluded Transarterial Chemoembolization (TACE) Using Miriplatin and Using Epirubicin for Hepatocellular Carcinoma: A Retrospective Study of 62 Cases

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Abstract

Purpose: This study aimed to retrospectively compare the local control and safety of microballoon-occluded transarterial chemoembolization (B-TACE) using miriplatin (MPT) and of conventional TACE (C-TACE) using epirubicin (EPIR) for hepatocellular carcinoma (HCC).

Materials and Methods: Thirty-nine patients (24 men, 15 women; mean age, 73.4 years) were treated using B-TACE with MPT (MPT-B-TACE group). As a historical comparison, 23 patients (13 men, 10 women; mean age, 72.2 years) who were treated using C-TACE with EPIR (EPIR-C-TACE group) were investigated. The therapeutic effect within 2 weeks after treatment was compared between the groups based on the Response Evaluation Criteria in Cancer of the Liver (RECICL), and time to local recurrence was compared based on the Kaplan-Meier method and log-rank tests. The side effects were compared based on the Common Terminology Criteria for Adverse Events (ver. 4.0).

Results: No significant differences were noted in patients’ characteristics between the groups. The overall incidence of postembolization syndrome was significantly lower in the MPT-B-TACE group than in the EPIR-C-TACE group (p<0.05), but two cases in the MPT-B-TACE group developed grade 2 cholecystitis. Based on the RECICL, the objective response rate, including TE4 and TE3, within 2 weeks after treatment was significantly higher in the MPT-B-TACE group (89.7%) than in the EPIR-C-TACE group (78.3%). Overall, local recurrence was significantly less frequent in the MPT-B-TACE group than in the EPIR-C-TACE group (p=0.02).

Conclusion: MPT-B-TACE was associated with a higher objective response rate and lower local recurrence rate than EPIR-C-TACE without a significant increase in adverse effects.

Key words: hepatocellular carcinoma, microballoon-occluded transarterial chemoembolization, miriplatin

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INTRODUCTION

Transarterial chemoembolization (TACE) is an effective palliative treatment option for patients with hepatocellular carcinoma (HCC) that is not resectable or that cannot be treated with percutaneous interventions, with proven improvement in survival in selected patients [1-5]. Although many chemotherapeutic agents, including doxorubicin, epirubicin, mitomycin C, and cisplatin, are used with an oil-based contrast agent (e.g., Lipiodol, Guerbet Japan, Tokyo, Japan), the best choices for first- and second-line drugs for TACE remain uncertain [6-8]. With advances in microcatheter and guidewire technology, the tumor-feeding branch can be selected in almost all patients, and the local control effects of TACE have been improved [5]. Since 2011, a 2.0-Fr microballoon catheter has been available for selective TACE treatment of HCC [9]. Microballoon-occluded transarterial chemoembolization (B-TACE) was shown to induce dense iodized oil accumulation in HCC nodules [10]. Under microballoon occlusion, this may be due to the hemodynamic change in the treated liver segment, forceful retrograde injection of embolic agents into collateral vessels, and prevention of embolic agent migration into other hepatic arteries [10].

Miriplatin (MPT) (Miripla, Dainippon Sumitomo Pharma, Osaka, Japan) is a lipophilic platinum complex that is theoretically a good candidate for an anticancer agent in TACE because of its lipophilicity and sustained release [11, 12]. However, in clinical practice, many radiologists have pointed out that injection of MPT-Lipiodol suspension (MLS) requires unusually high pressure through a microcatheter system, and the drug leaves the tumor quickly after embolization and has a lower local control effect for HCCs than other anticancer agents due to its high viscosity [13, 14]. To the best of our knowledge, reports on the therapeutic effects of B-TACE with MPT (MPT-B-TACE) compared with those of conventional TACE with epirubicin (EPIR; Nippon Kayaku, Tokyo, Japan) are yet to be available. This retrospective study aimed to compare the short-term local control effects of MPT-B-TACE for HCCs with those of conventional TACE with epirubicin (EPIR-C-TACE).

MATERIALS AND METHODS

This retrospective study was performed with the approval of our institutional review board, and written informed consent was obtained from all patients.

Patients

In our institutions, TACE was indicated for patients with a limited number of HCC nodules when percutaneous radiofrequency ablation therapy (RFA), percutaneous ethanol injection therapy (PEIT), or surgical resection was not indicated. The contraindications to RFA or PEIT are as follows: lesion larger than 3 cm; lesions adjacent to the gallbladder, stomach, common biliary duct, and colon; and lesions in a difficult location for needle placement. The medical records and radiological images of 90 consecutive patients who underwent TACE for unresectable HCCs at our institution from November 2011 to January 2014 were reviewed. A total of 8 patients with hypovascular HCCs, 12 patients with HCC treated with RFA after TACE, and 8 patients who lacked follow-up data were excluded. Consequently, this study included 62 patients (25 women and 37 men; mean age, 72.4 years; range, 57-87 years) with HCCs treated with EPIR-C-TACE or MPT-B-TACE. As a historical control group, the EPIR-C-TACE group consisted of 23 patients who were treated with conventional TACE using EPIR from November 2011 to October 2012 (13 men, 10 women; mean age 71.3 ± 8.9 years). The MPT-B-TACE group consisted of 39 patients who were treated with B-TACE using MPT from November 2012 to January 2014 (23 men, 15 women; mean age 73.9 ± 9.0 years). Selection of treatment methods was not randomized and was divided historically. All target HCCs were new lesions and were not treated previously.

The pre procedural diagnosis of HCC was established based on findings of contrast [370 mg I/ml iopamidol (Iopamiron 370; Bayer Schering Pharma, Osaka, Japan; Omnipaque 350, Daiichi-Sankyo, Tokyo, Japan)]-enhanced dynamic computed tomography (CT) [Aquilion 64 (Toshiba, Tokyo, Japan) or SOMATOM Sensation 64-slice Configuration (Siemens, Germany)] imaging and/or gadolinium-ethoxybenzyl-diethylenetriamine pentaacetic acid (Gd-EOB-DTPA; Primovist, Bayer Schering Pharma, Osaka, Japan)-enhanced magnetic resonance imaging (MRI; MAGNETOM ESSENZA 1.5T, Siemens) showing characteristic homogeneous or mosaic-like nodular enhancement in the arterial phase and washout in the delayed phase.

The patients’ characteristics before TACE are summarized in Table 1.

Procedure of MPT-B-TACE

A 4F or 5F hook-shaped guiding catheter was placed in the celiac or common hepatic artery. The microballoon catheter (LOGOS; 1.8 Fr tip, PIOLAX, Tokyo, Japan or Attendant LP 3.0 Fr tip or Nexus; 1.9 Fr tip, Terumo Clinical Supply, Gifu, Japan) was placed at the segmental or subsegmental artery of the hepatic artery via the guiding catheter to perform B-TACE. The maximum balloon diameter was 4 mm, and the microballoon catheter was introduced over a 0.014-inch guide wire (Labyrinth; PIOLAX, Tokyo, Japan, or GT wire, Terumo Clinical Supply). The balloon was inflated to a diameter 5-10% larger than that of the occluded artery. Under microballoon occlusion, selective angiography was performed, and feeding arteries and tumor stains of the target lesions were identified. Before treatment, only angiography was performed.

The MLS was prepared by dissolving 60 mg MPT (maximum dose: 120 mg) in 3.5 ml lipiodol (maximum dose: 7 ml). The MLS was warmed to 40 °C [15,16] and was immediately administered via transarterial infusion after balloon
Table 1. Patients’ Characteristics

<table>
<thead>
<tr>
<th></th>
<th>MPT-B-TACE (n=39)</th>
<th>EPIR-C-TACE (n=23)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male/Female</td>
<td>24/15</td>
<td>13/10</td>
</tr>
<tr>
<td>Age (years old)</td>
<td>73.9 ±9.0 (59-87)</td>
<td>71.3±8.9 (57-82)</td>
</tr>
<tr>
<td>Child–Pugh class (A/B/C)</td>
<td>25/12/2</td>
<td>14/9/0</td>
</tr>
<tr>
<td>Background liver (HBV/HCV/NBNC)</td>
<td>20/17/2</td>
<td>11/9/3</td>
</tr>
<tr>
<td>Main tumor size (cm)</td>
<td>2.9±1.5 (1.3-6)</td>
<td>2.8±1.2 (1.0-6)</td>
</tr>
<tr>
<td>Number of Tumor (1/2/3/Multiple)</td>
<td>24/ 7/2/6</td>
<td>10/3/3/7</td>
</tr>
<tr>
<td>Des-g-carboxyprothrombin (AU/l)</td>
<td>2331±1514 (19-13378)</td>
<td>2473±1605 (107 -25038)</td>
</tr>
<tr>
<td>AFP (U/mL)</td>
<td>1500±843 (32.4-28400)</td>
<td>1687.4±868.7 (78.3-24870)</td>
</tr>
<tr>
<td>Previous TACE/RFA/Ope</td>
<td>22/6/6</td>
<td>9/2/4</td>
</tr>
<tr>
<td>Treatment area</td>
<td>Subsegmental/Segmental/Lobe/whole liver</td>
<td>7/27/2/3</td>
</tr>
<tr>
<td>Treated vessels</td>
<td>Subsegmental / segmental</td>
<td>12/27</td>
</tr>
<tr>
<td>Dose of administrated anti-cancer drug (mg)</td>
<td>51.4±21.9 (20-120)</td>
<td>25.6±10.1 (15-50)</td>
</tr>
<tr>
<td>Dose of lipiodol (ml)</td>
<td>3.1±1.2 (1.2-7)</td>
<td>3.2±1.7 (1.5-6)</td>
</tr>
</tbody>
</table>

Mean ± SD (minimum-maximum).

Note: MPT-B-TACE, balloon-occluded transcatheter arterial chemoembolization using miriplatin; C-TACE, conventional transcatheter arterial chemoembolization using epirubicin, HBV, hepatitis B virus; HCV, hepatitis C virus; Tumor size: Max diameter of tumor; PIVKA-II protein induced in vitamin K absence II; AFP: alfa-fetoprotein; n.s., not significant.

inflation. The MLS infusion was continued under balloon occlusion until the HCC nodule was filled with the MLS or portal venous branches or intersegmental anastomoses of the hepatic artery were beginning to be filled with MLS. Then, fragmented gelatin particles (Gelpart; 1 mm in diameter, Nippon Kayaku, Tokyo, Japan), which were fragmented into small sizes of 150-200 μm long by pumping between two syringes 10 times using a three-way stopcock, were infused until they filled the arterial branches beyond the catheter tip. In all cases of this study, the balloon was inflated from the start of MLS infusion to the end of gelatin particle infusion regardless of change of tumor stain under balloon occlusion. The doses of the MLS and gelatin sponge were determined based on tumor size and the degree of hepatic reserve. The lipiodol deposit in the target HCCs was not checked on CT-like image after treatment.

Procedure of EPIR-C-TACE

A 4F hook-shaped guiding catheter was placed in the celiac or common hepatic artery. Microcatheters (Sniper 2, 2.1 Fr tip, Terumo Clinical Supply) were inserted into the tumor-feeding artery as peripherally as possible and positioned in the subsegmental or segmental branch of the artery. Before treatment, only angiography was performed. An
EPIR and lipiodol (2-7 ml iodized oil) emulsion, a contrast medium (Iopamiron 300, Bayer Yakuhin, Osaka, Japan or Omnipaque 300, Daiichi-Sankyo) of 1/3 iodized oil, and EPIR (10-40 mg) were mixed by pumping 10 times using a three-way stopcock valve and two 10-ml syringes. The EPIR and lipiodol emulsion was infused until the HCC nodule was filled with emulsion or portal venous branches were beginning to be filled with emulsion. Then, the fragmented gelatin particles sized 150-200 μm long were infused until they filled the arterial branches beyond the catheter tip. The doses of emulsion and gelatin sponge were determined based on tumor size and the degree of hepatic reserve. In this study, the lipiodol deposit in the target HCCs was not checked on CT-like image after treatment.

Assessments

Evaluation of therapeutic outcomes

The therapeutic effect within 2 weeks after MPT-B-TACE and EPIR-C-TACE was evaluated based on the findings on contrast-enhanced dynamic CT. Two experienced radiologists, who were blinded to the TACE methods, assessed the therapeutic effects on target HCCs by consensus. Response categories, according to the Response Evaluation Criteria in Cancer of the Liver (ver. 5.12) [17], were as follows: TE1 (tumor enlargement more than 25%), TE2 (tumor response between TE1 and TE3), TE3 (tumor necrosis or dense lipiodol accumulation of more than 50%), and TE4 (diffuse accumulation of lipiodol associated with tumor size reduction).

Time to local recurrence after TACE was evaluated via dynamic CT and/or EOB-enhanced MRI 1-3 months after TACE. Local recurrence was defined as an early enhancing tumor without iodized oil accumulation in or adjacent to the tumor, and it was classified into two patterns: intratumoral recurrence (IR) and peritumoral recurrence (PR) (Fig. 1) [5, 14]. IR was defined as viable tumor corresponding to a defect in which iodized oil had previously accumulated. PR was defined as a recurrent tumor adjacent to a treated tumor with accumulation of iodized oil without a defect.

Toxicity evaluation

Treatment-related toxicity was assessed using the Common Terminology Criteria Adverse Event (ver. 4.0). Adverse events (AEs) were evaluated as the maximum change in the grade within 2 weeks after TACE.

Statistical analysis

The patients’ characteristics and treatment procedures were compared between the MPT-B-TACE group and the EPIR-C-TACE using the χ2 test or Mann-Whitney U-test, as appropriate. Treatment responses and AEs were also compared between the two groups using the χ2 test or Mann-Whitney U-test, as appropriate. The incidence of cumulative local recurrence was calculated using the Kaplan-Meier method and compared using the log-rank test. The generalized Wilcoxon test was used to evaluate significant differences in each group. Values of p<0.05 were considered significant. Statistical calculations were performed using JMP (version 9.0; SAS Institute, Cary, NC).

RESULTS

The patients’ characteristics and treatment results are summarized in Table 1. No significant differences in age, sex, underlying liver disease, number of tumors, tumor marker, Child-Pugh score, history of previous treatment, and tumor size were noted between the MPT-B-TACE and EPIR-C-TACE groups. Subsegmental treatment tended to be performed less often in the MPT-B-TACE group than in the EPIR-C-TACE group.

In terms of the therapeutic effect within 2 weeks after MPT-B-TACE and EPIR-C-TACE evaluated on CT examinations, the objective response rate, including TE4 and TE3, was significantly higher in the MPT-B-TACE group (89.7%) than in the EPIR-C-TACE group (78.3%, p=0.02). The median follow-up periods were 248 days (range, 45-665) for subjects receiving MPT-B-TACE and 127 days (range, 30-365) for those receiving EPIR-C-TACE. Overall, the Kaplan-Meier analysis showed that local recurrence was significantly less common in the MPT-B-TACE group (89.7%) than in the EPIR-C-TACE group (78.3%, p=0.02). At the time of the analysis, the local recurrence rate tended to be lower in the MPT-B-TACE group (64%) than in the EPIR-C-TACE group (78.3%). Among recurrent tumors, IR occurred in 10 of the 18 patients (55.6%) in the EPIR-C-TACE group and in 13 of the 25 patients (52%) in the MPT-B-TACE group. Most IR tumors in the MPT-B-TACE group were larger than 5 cm HCCs, and 80% of cases in the EPIR-C-TACE had more than 3 HCCs. No significant differences in IR were noted between the two groups.
Table 2. Therapeutic effect at two weeks after MPT-B-TACE and EPIR-C-TACE

<table>
<thead>
<tr>
<th></th>
<th>MPT-B-TACE group (n=39)</th>
<th>EPIR-C-TACE group (n=23)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TE4</td>
<td>29 (74.3%)</td>
<td>9 (39.1%)</td>
</tr>
<tr>
<td>TE3</td>
<td>6 (15.4%)</td>
<td>9 (39.1%)</td>
</tr>
<tr>
<td>TE2</td>
<td>3 (7.7%)</td>
<td>5 (21.7%)</td>
</tr>
<tr>
<td>TE1</td>
<td>1 (2.6%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

MPT-B-TACE, balloon-occluded transcatheter arterial chemoembolization using miriplatin; C-TACE, conventional transcatheter arterial chemoembolization using epirubicin; TE, treatment effect.

Adverse events

The results for AEs classified according to CTCAE 4.0 are summarized in Table 2. The overall incidence of postembolization syndrome was significantly lower in the MPT-B-TACE group than in the EPIR-C-TACE group (p<0.05). No significant differences in the overall incidence of other AEs were noted between the two groups. In the MPT-B-TACE group, two patients developed grade 2 cholecystitis, but it resolved with conservative treatment. A representative case is shown in Figure 2. On the digital fluorography recorded during B-TACE via A6, dense lipiodol deposition in the HCC could be seen, and lipiodol migration into the cystic artery was not evident (Figure 2d). On the final celiac arteriogram after B-TACE, the distal side of the cystic artery was poorly visualized. On the day after treatment, the patient complained of abdominal pain and had increased hepatobiliary enzymes. Unenhanced CT obtained on the day after treatment showed gallbladder wall edema (Figure 2f), and acute cholecystitis was diagnosed. The cholecystitis improved with conservative treatment without cholecystectomy. Biloma after MPT-B-TACE was not noted; however, forceful injection of embolic agents might be a risk for excess embolization and biloma formation. No patients in either group had severe AEs or died during follow-up after TACE.

DISCUSSION

TACE has been widely performed in patients with unresectable HCCs, and previous randomized controlled trials and meta-analyses confirmed the survival benefit of TACE. The most effective and least toxic agents or protocols for the treatment of HCC remain unclear because many anticancer drugs, such as doxorubicin, epirubicin, mitomycin C, and cisplatin, have been used [18, 19]. For TACE, using emulsions of chemotherapeutic agents, such as epirubicin, cisplatin, or iodized oil, is recommended to enhance the anticancer effects [20, 21]. To maximize the therapeutic effect of TACE, anticancer agents with high solubility and stability in lipiodol and those that have gradual release within tumors are considered ideal. Pharmacokinetic studies have demonstrated that the plasma concentration of total platinum is considerably lower in patients treated with MPT compared with that in patients treated with intra-arterial cisplatin. MLS is a stable colloidal emulsion that is deposited within HCC tumors, where it gradually releases active derivatives of MPT [16]. MPT is theoretically a good candidate for this kind of agent [22, 23], although no strong evidence is available. However, in actual clinical practice, many physicians have pointed out that MLS injection requires unusually high pressure, particularly through a microcatheter system, due to its high viscosity [24-27]. This results in lower local control compared with a lipiodol emulsion with conventional chemotherapeutic agents. To resolve this treatment difficulty, B-TACE was performed with an MLS. In most of our cases, good lipiodol accumulation and local control effects were obtained after MPT-B-TACE. Under microballoon occlusion, hemodynamic changes can be obtained in the treatment area of liver parenchyma and target HCCs [10]. In some cases, during MPT-B-TACE, the MLS was infused into small feeding arteries, which could not be identified during arteriography before treatment. Additionally, migration of MLS and gelatin sponge particles into other hepatic arteries could be prevented by the microballoon. Therefore, we could infuse enough MLS and gelatin sponge particles into the target HCCs and obtain good lipiodol accumulation in most target HCCs after MPT-B-TACE. In many cases, a better local control effect could be obtained after MPT-B-TACE during follow-up.

However, local recurrence occurred in 35% of cases in the MPT-B-TACE group during follow-up (median: 122 days). Among recurrent tumors, IR was predominant, occurring in 55.6% of patients in the MPT-B-TACE group. Most IR tumors were large and multiple HCCs, which may be
MPT is considered to cause few systemic adverse reactions because it remains locally in tumors for a long period of time and it is transferred minimally to the systemic circulation [28, 30, 31]. Thus, even if local drug uptake is enhanced by B-TACE, a small systemic effect may be possible. Additionally, compared with C-TACE, lipiodol and embolic agents could be injected under balloon occlusion more effectively because of the decreased pressure gradient between the occluded artery and portal vein [10, 29]. MPT-B-TACE induced few AEs, although two cholecystitis (grade 2) cases were encountered. During B-TACE, forceful injection of lipiodol suspension and embolic agents can be performed under balloon occlusion; therefore, lipiodol and embolic agents migrate into the cystic artery via collateral pathways, and cholecystitis occurred. Physicians must recognize the risk of nontarget embolization, such as cholecystitis, because of migration of embolic agents into the cystic artery via collateral pathways. In particular, physicians must identify the cystic artery before treatment and carefully detect migration of lipiodol during B-TACE. In the present study, biloma after MPT-B-TACE did not occur; however, forceful injection of embolic agents might be a risk for excess embolization and biloma formation.

With regard to AEs, significantly fewer patients had abdominal pain and nausea/vomiting in the MPT-B-TACE group than in the EPIR-C-TACE group. Additionally, most AEs tended to be fewer in the MPT-B-TACE group than in the EPIR-C-TACE group. MPT is considered to cause few
This study has some limitations. It was retrospective and non-randomized, and the sample size was fairly small. Additionally, local recurrence in the EPIR-C-TACE group tended to be higher than in previous reports of EPIR-C-TACE. The median time to local recurrence of EPIR-C-TACE also tended to be shorter than the median time to progression in previous report (3.9 months vs 7.8 months, respectively) [32]. This is possibly because the number of
Table 3. Adverse events after TACE classified by CTCAE 4.0

<table>
<thead>
<tr>
<th>Event</th>
<th>All Grade (%)</th>
<th>Grade 1</th>
<th>Grade 2</th>
<th>Grade 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MPT</td>
<td>EPIR</td>
<td>MPT</td>
<td>EPIR</td>
</tr>
<tr>
<td>Pain</td>
<td>23.1</td>
<td>52.2</td>
<td>9</td>
<td>11</td>
</tr>
<tr>
<td>Nausea, Vomiting</td>
<td>12.8</td>
<td>52.2</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td>Fever</td>
<td>25.6</td>
<td>43.5</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Leucopenia</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Ascites</td>
<td>5.1</td>
<td>13.0</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>5.1</td>
<td>13.0</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Cholangitis</td>
<td>5.1</td>
<td>13.0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Elevated AST, ALT</td>
<td>43.6</td>
<td>69.6</td>
<td>15</td>
<td>13</td>
</tr>
<tr>
<td>Elevated Bilirubin</td>
<td>30.8</td>
<td>43.5</td>
<td>12</td>
<td>10</td>
</tr>
</tbody>
</table>

Note: MPT, MPT-B-TACE group; EPIR, EPIR-C-TACE group

Numbers in parentheses denote the number of cases categorised as each grade according to the National Cancer Institute Common Terminology Criteria (version 4.0). Gr, Grade; AST, aspartate aminotransferase; ALT, alanine aminotransferase.

...patients in our EPIR-C-TACE group who could be treated with superselective TACE might have been fewer than in previous reports. The local control rate after MPT-B-TACE in the present study (median time to local recurrence, 8.3 M) might be comparable with previous reports regarding C-TACE using MPT and EPIR [14, 32], but the present data tended to be lower than in previous reports regarding MPT-B-TACE [28, 33, 34]. This might be possibly caused by patient and tumor characteristics. However, all procedures in the present study were performed by the same physician, and the local control effect after MPT-B-TACE was improved significantly compared with that of our previous EPIR-C-TACE, without severe AEs. To establish the long-term efficacy of MPT-B-TACE for HCC, more studies and clinical experience with this treatment are needed.

In conclusion, MPT-B-TACE was associated with a higher objective response rate and a lower local recurrence rate than EPIR-C-TACE, with a lower rate of postembolization syndrome. These results are encouraging, but firm conclusions cannot be drawn because of the small number of patients studied.

Conflict of interest: We have no direct or indirect financial interest in the products under investigation or subject matter discussed in this manuscript.

This study has been presented at RSNA 2014.

References


