Comparison of Yttrium-90 Radioembolization and Transcatheter Arterial Chemoembolization for the Treatment of Unresectable Hepatocellular Carcinoma

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PURPOSE: To compare the effectiveness and toxicity of transcatheter arterial chemoembolization (chemoembolization) and yttrium-90–labeled microspheres (radioembolization) in patients with unresectable hepatocellular carcinoma (HCC).

MATERIALS AND METHODS: Outcomes from patients who underwent radioembolization or chemoembolization as the only treatment for unresectable HCC from 1996 to 2006 were compared. Response was assessed with Response Evaluation Criteria in Solid Tumors, survival was assessed with the Kaplan-Meier method, and toxicity was graded with National Cancer Institute criteria. Multivariate analysis for factors affecting survival was performed.

RESULTS: Seventy-one patients were treated with either chemoembolization (n = 44, 62%) or radioembolization (n = 27, 38%). Treatment groups were similar in age, sex, Child class, Model for End-Stage Liver Disease score, tumor size, and vascular invasion. Progressive disease at 3 months was observed in 16 (36%) of the 44 patients treated with chemoembolization and nine (33%) of the 27 patients treated with radioembolization (P not statistically significant). The median overall survival was similar for both groups (6 months with chemoembolization vs 6 months with radioembolization, P = .7). Grade 3 or higher toxicity was observed in 24 of the 71 patients (34%). Tumor multifocality, vascular invasion, and hepatitis C seropositivity were independently associated with worse survival, whereas method of treatment was not.

CONCLUSIONS: In this single-center study, preliminary evidence suggests that chemoembolization and radioembolization provided similar effectiveness and toxicity in patients with unresectable HCC.


Abbreviations: AFP = α-fetoprotein, HCC = hepatocellular carcinoma, HCV = hepatitis C virus, MELD = Model for End-Stage Liver Disease, 90Y = yttrium-90

HEPATOCELLULAR carcinoma (HCC) is one of the most common solid organ cancers in the world, with the number of new cases exceeding 600,000 annually (1,2). Partial hepatectomy and orthotopic liver transplantation remain the best options for potential cure for patients diagnosed with HCC (3–5); however, most patients present with either unresectable (intermediate or advanced) tumors, cirrhosis, or both, eliminating these surgical treatment choices (1,6,7). Limited effectiveness and high toxicities of systemic chemotherapy combined with the propensity for unresectable HCC to manifest with disease confined to the liver have driven the development of regional therapeutic approaches.

Chemoembolization is the most well-examined and commonly used form of regional treatment for unresectable HCC. Chemotherapeutic agents are infused via the hepatic arterial blood supply through percutaneously placed transarterial catheters, and this is usually followed by selective arterial embolization of the tumor vascular supply. Embolization results in tumor necrosis, potentiating the cytotoxic effects of the chemotherapy. In many protocols, the combination of Adriamycin, Mitomycin C, and cisplatin is employed; however, there is considerable variability in this regard. Prospective studies demonstrate that chemoembolization can provide symptomatic improvement and a potential survival advantage over the best
supportive care for patients with intermediate HCC (8,9); however, existing randomized trials are small, and meta-analyses suggest only marginal benefits of chemoembolization (10–12).

A newer regional technique is radioembolization. This modality involves the arterial infusion of glass or resin microspheres labeled with a radiotherapeutic agent (most commonly yttrium-90 [90Y]), which are similarly administered via percutaneously placed catheters positioned in the hepatic arterial system. Radioembolization is a form of brachytherapy that allows for concentrated beta-radiation administration to tumor tissue while minimizing damage to surrounding liver parenchyma (13,14). It appears to be somewhat tumor-selective based on natural disruptions to the micro-vasculature surrounding liver tumors (15,16) and can be delivered selectively with segmental, lobar, or whole-liver approaches (17). Radioembolization appears to rely less on static arterial embolization than chemoembolization and, as such, may induce less hepatocyte damage in patients with impaired baseline liver function and therefore be preferable in patients with portal vein tumor thrombus (18).

To date, there are a paucity of data comparing outcomes for patients with HCC treated with either chemoembolization or radioembolization. A comparison of these two approaches may help identify subsets of patients who can benefit more from one approach over the other. The purpose of this study was to compare effectiveness and toxicity profiles of chemoembolization and radioembolization with 90Y microspheres for regional therapy in patients with unresectable HCC.

MATERIALS AND METHODS

Patient Selection and Data Sources

With internal review board approval, all patients with a diagnosis of HCC who underwent chemoembolization or radioembolization between January 1, 1996, and December 31, 2006, at one institution were identified. Patients were eligible for inclusion if they had histologically confirmed HCC or cirrhosis with consistent radiographic tumor findings, if they had an elevated α-fetoprotein (AFP) level (>400 ng/mL [>400 μg/L]), and if they were deemed unsuitable for resection or transplantation. This included patients with multifocal cancer falling outside the Milan criteria (4) and patients with cirrhosis who were deemed unsuitable for resection, transplantation, or ablation upon review in a multidisciplinary hepatobiliary tumor conference. Main portal vein tumor thrombus was a contraindication for therapy, whereas treatment of branch portal vein disease was permitted. Patients had to have malignancy confined to the liver and been treated with only chemoembolization or radioembolization but may have had multiple sessions of that same therapy over time. In this study there were no patients that received both forms of therapy, and no patient went on to receive sorafenib (Nexavar; Bayer, Pittsburgh, Pennsylvania) therapy.

As radioembolization was first used at our institution in January of 2003, data from a prospectively maintained database of patients treated with radioembolization (2003 to present) were compared with those from a retrospective database of patients treated with chemoembolization (1996 to present). Hospital and outpatient records for each identified patient were examined to verify disease status, treatment response, toxicity of therapy, and survival. Patients were contacted with letters and follow-up telephone calls, according to a scripted protocol approved by institutional review board.

As no defined criteria exist for selecting one form of regional therapy over the other, hard criteria for choice of therapy cannot be provided and no rigid algorithm was used to make this decision. Instead, cases were all discussed individually at a multidisciplinary gastrointestinal tumor conference. Our group has preferentially treated patients with major vessel with radioembolization, as hepatic arterial stasis may play less of a role in this approach.

Chemoembolization

Chemoembolization was performed in the angiography suite, with patients under moderate sedation, according to the following protocol. Mesenteric arteriography was performed to assess arterial anatomy, tumor burden, vascularity, portal venous patency, and arteriovenous shunting. Selective arterial catheterization was performed with microcatheters according to the clinical situation, extent of disease, and patient fitness. A standard combination of three hydrophilic chemotherapeutic agents, 50 mg of doxorubicin (Adriamycin; Pharmacia & Upjohn, Peapac, New Jersey), 100 mg of cisplatin (Platino; Baxter, Glendale, California), and 8 mg of mitomycin (Mitomycin-C; Super Glen, Dublin, California), was mixed 1:1 in an emulsion with iodized oil (Ethiodol; Savage Laboratories, Melville, New York). The amount of this mixture administered varied according to the volume of liver tumor being treated. Embolization was then performed with polyvinyl alcohol particles (150–250 μm in diameter). The amount of particulate embolization also varied with underlying factors such as presence or absence of main branch portal or hepatic venous tumor invasion.

Radioembolization

The use of SIR Spheres (SIRTex Medical, New South Wales, Australia) for HCC is off label by the U.S. Food and Drug Administration. All patients underwent superior mesenteric and celiac angiography to define the arterial supply of the liver, HCC, and stomach. Potential hepaticenteric arterial communications were investigated (gastroduodenal, supraduodenal, retroduodenal, right or accessory gastric, falciform, and accessory or inferior phrenic arteries) and embolized with coils to prevent unintended radiation-induced injuries. The gastroduodenal artery was embolized in each case. Other vessels were embolized selectively if identified, but this was uncommonly performed. After protective coil embolization, 4–5 mCi (148–185 MBq) of technetium 99m-macroaggregated albumin was injected in the proper hepatic artery and scintigraphy performed to detect arteriovenous shunting and lung shunt fraction in all patients. The shunt fraction was defined as the proportion of total lung counts to total lung and total liver counts. A pulmonary shunt fraction of less than 20% was considered acceptable for treatment (19,20). In this experience, two patients were denied radioembolization because of a shunt fraction exceeding 20%.

Therapy was administered as previously described (21). Briefly, radioembolization was performed via a 3-F mi-
crocatheater by using a lobar approach with $^{90}$Y resin-based microspheres (SIR-Spheres). The $^{90}$Y dose was based on the extent of tumor involvement in the liver, which was calculated by using computerized tomography (CT) or magnetic resonance volumetric imaging, adjusted by lung shunt fraction. The diameter of resin-based $^{90}$Y was about 29–35 μm, with average activity of 40 Bq per microsphere. The actual dose was calculated by using the body surface area method, decreased by the degree of lung shunting. The body surface area was calculated in square meters as $0.20247 \times (\text{height} \times 0.725 \text{ m}) \times (\text{weight} \times 0.425 \text{ kg})$. Tumor involvement was calculated as (tumor volume $\times 100$)/ (tumor volume + liver volume). The actual dose (in gigabecquerels) was calculated as (body surface area − 0.2) + (tumor involvement/100). Microsphere administration was performed in an angiography suite with a standard angiographic technique similar to that of chemoembolization. A microcatheter was placed in either the right or left hepatic artery before the administration of $^{90}$Y. The administration of $^{90}$Y was alternated with the infusion of sterile water and iodinated contrast medium. Contrast medium was used to visualize under fluoroscopy and monitor the status of flow to the treating tumor and feeding vessel. Sufficient pressure should be applied during the administration to keep $^{90}$Y adequately suspended in sterile water. The endpoint of the injection was either delivering the entire calculated and supplied dose (20–60 mCi[740–2,220 MBq] per lobe treated) or reaching the vascular flow stasis. Contrast medium was used to visualize under fluoroscopy and monitor the status of flow to the treating tumor and feeding vessel. Sufficient pressure should be applied during the administration to keep $^{90}$Y adequately suspended in sterile water. The endpoint of the injection was either delivering the entire calculated and supplied dose (20–60 mCi[740–2,220 MBq] per lobe treated) or reaching the vascular flow stasis. Once ves-

crocatheater by using a lobar approach with $^{90}$Y resin-based microspheres (SIR-

treatment was the focus of this study. Inclusion was limited to angiography suite patients who underwent chemoembolization (n = 44, 62%) or radioembolization (n = 27, 38%) as their only form of directed treatment (radiofrequency ablation, cryoablation, or percutaneous ethanol injection). The subgroup of 71 patients who underwent chemoembolization (n = 44, 62%) or radioembolization (n = 27, 38%) as their only form of therapy was the focus of this study. Clinicopathologic characteristics of the 71 patients are summarized in Table 1. There were no significant differences between the groups with regard to

**Patient Characteristics**

Clinicopathologic variables were evaluated. Variables assessed included age, sex, ethnicity (white, black, other), hepatitis C virus (HCV) serology (positive or negative), pretreatment AFP levels, tumor size (of the largest lesion) and burden (solitary vs multifocal), Child-Pugh class, unadjusted (laboratory) Model for End-Stage Liver Disease (MELD) score (22), Okuda stage, and presence or absence of main branch portal or hepatic venous invasion.

**Treatment Effect**

Patients were evaluated for treatment response with helical three-phase, thin-cut CT 4 weeks after treatment and then every 12 weeks if stable. Patients receiving incomplete treatment at the first setting were re-treated at 4 weeks and then assessed 12 weeks later. Tu-

**Survival and Multivariate Analysis**

Overall survival was calculated starting from the time of initial treatment up until the date of the last follow-up or death. Mortality data were collected from hospital medical records, from the Social Security Death Index interactive search engine, and through telephone contact. Because all patients had unresectable malignancy and/or unresectable cirrhosis, overall survival and disease-specific survival were similar; thus, overall survival is reported. Multivariate analysis of factors potentially bearing independent association with overall survival was performed, including dichotomous disease and treatment variables.

**Toxicity**

To standardize reporting, treatment complications were graded on a scale of 1 to 5 according to the National Cancer Institute’s Common Terminology Criteria for Adverse Events (version 3.0) (23). In particular, mild, moderate, severe, and life-threatening or disabling toxicity were represented by grades 1, 2, 3, and 4, respectively. Toxicity resulting in death was considered grade 5. For stratification, anything over a grade 2 event was assessed as a “major” toxicity. Specific categories of toxicities were also assessed. Treatment-related toxicity within 30 days of the first embolization is reported.

**Statistical Analysis**

Data were analyzed and outcomes evaluated for all patients in both treatment groups. The Fisher exact and Student t tests were used to compare categoric and continuous variables between the two groups, respectively. Overall survival curves for each variable were generated with the Kaplan-Meier technique. Differences in survival curves were assessed by using the log-rank test. Multivariable stratified Cox regression was used to evaluate the association between multiple variables and survival. A P value of less than .05 was considered to be statistically significant. The statistical analysis of results was performed with the aid of SPSS 15.0 software (SPSS, Chicago, Illinois).

**RESULTS**

**Patient Characteristics**

Of the 135 patients treated with regional embolic therapy at our hospital during the specified time period, 93 (69%) underwent chemoembolization and 42 (31%) underwent radioembolization. The diagnosis was confirmed histologically by means of ultrasonographic or CT-guided fine-needle biopsy in 90 of the 135 patients (67%) and with clinical-radiologic findings with AFP determination (>400 ng/mL [>400 μg/L]) in 45 (33%). Sixty-four of the 135 patients (47%) underwent additional therapy with partial hepatectomy, liver transplantation, or other liver-directed treatment (radiofrequency ablation, cryoablation, or percutaneous ethanol injection). The subgroup of 71 patients who underwent chemoembolization (n = 44, 62%) or radioembolization (n = 27, 38%) as their only form of therapy was the focus of this study.

Clinicopathologic characteristics of the 71 patients are summarized in Table 1. There were no significant differences between the groups with regard to
Treatment Effectiveness

Results of therapy are summarized in Table 2. On average, three post-therapy scans were obtained for each patient. Complete response was observed in only one patient treated with chemoembolization at 3 months. Partial response (≤50% reduction in largest tumor diameter) was observed in three (11%) of the 27 patients treated with radioembolization and two (4%) of the 44 patients treated with chemoembolization. The remaining patients had stable or progressive disease, and there were no significant differences between the treatment arms.

Assessment of treatment effectiveness with the evaluation of serum AFP concentration before and after treatment was studied in 21 patients treated with radioembolization and 42 treated with chemoembolization from the original patients identified. Five of the 21 patients treated with radioembolization (24%) demonstrated a greater than 30% decrease in AFP level from the pretreatment baseline value; 11 of the 42 patients treated with chemoembolization (26%) showed a similar response (data not shown).

The median follow-up for all patients was 6 months, which was the same for each treatment group. Median overall survival calculated from the date of treatment was not statistically different between the two groups (6 months with radioembolization and 6 months for chemoembolization; \( P = .74 \), Figure). Survival at 1 year from therapy was 16% (4/27) for patients treated with radioembolization and 20% (9/44) for patients treated with chemoembolization.

Multivariate analyses of disease and treatment factors for association with overall survival were performed, including the following dichotomized variables: HCV seropositivity (yes or no), Child-Pugh class (B or A), vascular invasion (yes or no), MELD score (>10 or ≤10), tumor distribution (bilateral or unilateral), and treatment type (radioembolization or chemoembolization). Variables maintaining independent association with poorer overall survival were HCV seropositivity, presence of macroscopic vascular invasion, and bilateral tumor distribution. The method of embolization (radioembolization vs chemoembolization) did not demonstrate association with survival (Table 3).

Toxicity

Duration of hospital stay, toxicity, and 30-day mortality for patients treated with radioembolization and chemoembolization are shown in Table 4. Following the first treatment, the average hospital stay was significantly longer for patients treated with chemoembolization. Overall toxicity was greater in patients treated with chemoembolization; however, the frequency of major toxicity (≥grade 3) was not different between the groups (radioembolization = 30%, chemoembolization = 36%; \( P = .61 \)). The 30-day mortality was less than 10% for both groups.

A categorized toxicity profile for both treatment groups is provided in Table 4. No statistically significant difference was observed in the frequency of gastrointestinal toxicity (nausea, vomiting, ulceration, abdominal pain, etc). Gastrointestinal toxicity was seen in 4 patients. Ulceration with confirmation of microspheres in the gastric mucosa was found in three of four radioembolization cases (two of which subsequently required subtotal gastrectomy), and gastritis with no evidence of spheres was found in the fourth case. Gastritis and/or temporary ulceration was observed in four patients treated with chemoembolization and nausea and/or vomiting was seen in five. These were treated with medical therapy only and resolved. There were more cases with hyperbilirubinemia (serum bilirubin level, ≥3.0 mg/dL [51.3 \( \mu\)mol/L]) in the chemoembolization group as compared with the radioembolization group (7/44 patients [16%] vs 1/27 patients [4%], \( P = .1 \)), but this difference did not reach statistical significance. Other liver-specific complications (transaminitis, encephalopathy, ascites) between radioembolization and chemoembolization groups were not different, but hematologic toxicity af-
fected chemoembolization patients exclusively. Ten patients treated with chemoembolization had neutropenia following therapy, and this was not observed following radioembolization. Of the 44 patients treated with chemoembolization, 30 had segmental therapy and 14 had more had nonselective right or left chemoembolization. Of these 14 patients, seven had temporary neutropenia, which subsequently resolved.

**DISCUSSION**

The purpose of this study was to compare efficacies and toxicities of two forms of regional therapy for unresectable HCC: chemoembolization, an established modality with modest benefit and a well-established toxicity profile, and radioembolization, which has more recently been approved for the treatment of primary and metastatic cancers of the liver.

The use of chemoembolization for unresectable HCC can be supported by two small randomized trials demonstrating benefit. Lo and colleagues (8) randomized 80 patients to receive chemoembolization (n = 40, iodized oil, cisplatin, and gelatin sponge) versus supportive care (n = 40) and found a reduction in the relative risk of death due to disease in the group treated with chemoembolization (relative risk = 0.49; 95% confidence interval = 0.29, 0.81; P = .006). That same year, the Barcelona group (9) reported their results of a three-arm trial where patients received supportive care (n = 35), bland embolization (n = 37, gelatin sponge), or chemoembolization (n = 40, gelatin sponge plus doxorubicin) and similarly found a disease-specific death reduction in the chemoembolization-treated arm when compared with the patients who received supportive care (relative risk = 0.45; 95% confidence interval = 0.25, 0.81; p = .02). Although these trials represent the best data for chemoembolization, both have limitations as each evaluate highly selected patients and are under-powered. Having stated this, chemoembolization is the best-investigated method by which other forms of regional therapy should be compared.

Radioembolization with 90Y microspheres exhibits low toxicity and may provide therapeutic benefit in the treatment of unresectable HCC (24). Radioembolization is not a new concept as experimentation with regional infusion of radioisotopes for unresectable liver cancer dates back to the 1970s (25,26). Initial experience with radiation-induced hepatitis and pneumonitis tempered enthusiasm for this approach, especially as the therapeutic window was thought to be small (27). Better understanding of the principles of shunt fraction and administration made this form of therapy more accessible (28,29). More recently, one randomized trial showed a progression-free benefit of radioembolization in patients with unresectable, liver-only colorectal cancer metastases (30), and radioembolization received Food and Drug Administration approval.

Data for radioembolization in the treatment of HCC exist, but results are varied and limited. An early analysis of a prospectively followed cohort of 20 patients treated with 90Y microspheres reported impressive outcomes with respect to both survival and quality of life (31). This report also addressed issues of super-selective administration, correlation of dose and survival, and shunt fraction. Subsequently, larger reports have surfaced supporting these earlier data (15,32). Although no prospective, randomized

### Table 2

**Results of Regional Therapy**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Radioembolization Group (n = 27)</th>
<th>Chemoembolization Group (n = 44)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of treatments</td>
<td>1.2 ± 1.1</td>
<td>1.3 ± 1.2</td>
<td>.53</td>
</tr>
<tr>
<td>Tumor response at 3 mo*</td>
<td></td>
<td></td>
<td>.73</td>
</tr>
<tr>
<td>Complete response</td>
<td>0 (0)</td>
<td>1 (2)</td>
<td></td>
</tr>
<tr>
<td>Partial response</td>
<td>3 (11)</td>
<td>2 (4)</td>
<td></td>
</tr>
<tr>
<td>Stable disease</td>
<td>11 (41)</td>
<td>16 (36)</td>
<td></td>
</tr>
<tr>
<td>Progressive disease</td>
<td>9 (33)</td>
<td>16 (36)</td>
<td></td>
</tr>
<tr>
<td>Patient survival after 1st treatment (mo)f</td>
<td></td>
<td></td>
<td>.74</td>
</tr>
<tr>
<td>Mean ± standard error</td>
<td>11.2 ± 2.8</td>
<td>9.8 ± 1.9</td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>6.0 (0–42)</td>
<td>6.0 (0–53)</td>
<td></td>
</tr>
<tr>
<td>Survival rate at 1 y</td>
<td>4/27 (16%)</td>
<td>9/44 (20%)</td>
<td></td>
</tr>
</tbody>
</table>

*Numbers in parentheses are percentages.

†Numbers in parentheses are the range.

*Results expressed as median (range).
Induction of tumor ischemia is not a part of this approach. Radioembolization, as vascular stasis is usual macroscopic vessel invasion with varying time periods during which the two groups were treated, as we compared a decade of chemoembolization to radioembolization (24). In comparing toxicity profiles of radioembolization and chemoembolization according to the National Cancer Institute common toxicity criteria, we found chemoembolization to be associated with statistically greater overall toxicity; however, no difference in the incidence of major toxicities between both groups was observed. Hematologic toxicity was observed exclusively in patients treated with chemoembolization, and, when comparing therapeutic options for individual patients, toxicity profile may be a deciding factor in choosing one option over another. To our knowledge, this comparative finding has not been reported.

We noted a significantly shorter length of stay for patients treated with radioembolization over chemoembolization, which may in part be due to toxicity but may also be due to the varying time periods during which the two groups were treated, as we compared a decade of chemoembolization patients with 3 years of radioembolization patients. Of note, radioembolization appears to be well tolerated with less pain and fever than chemoembolization, which may in part be due to toxicity but may also be due to the varying time periods during which the two groups were treated, as we compared a decade of chemoembolization to radioembolization (24). In comparing toxicity profiles of radioembolization and chemoembolization according to the National Cancer Institute common toxicity criteria, we found chemoembolization to be associated with statistically greater overall toxicity; however, no difference in the incidence of major toxicities between both groups was observed. Hematologic toxicity was observed exclusively in patients treated with radioembolization, and, when comparing therapeutic options for individual patients, toxicity profile may be a deciding factor in choosing one option over another. To our knowledge, this comparative finding has not been reported.

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with a relatively small number of patients (n = 71). Because it is not a randomized trial, selection bias and late-look bias are inherent. Furthermore, the patients in this experience had advanced HCC, rendering meaningful assessment of survival with respect to therapy choice more questionable. In addition, the time during which patients received chemoembolization spans 10 years (1996–2006), whereas all the radioembolization patients received their therapy between the years 2003 and 2006. Improvements in technology and increased scrutiny by insurers may have had an effect on some of the results in later years, which may have skewed results.

On the basis of our evaluation, radioembolization and chemoembolization appear to provide similar effectiveness, as defined by tumor response and patient survival, for patients with unresectable HCC. Major complication profiles were similar for both. Chemoembolization was associated with longer hospital stay than radioembolization patients received their therapy between the years 2003 and 2006. Chemoembolization was associated with longer hospital stay than radioembolization patients received their therapy between the years 2003 and 2006. On the basis of this analysis, there does not appear to be a substantial difference between treatment with radioembolization or chemoembolization in patients with unresectable HCC.

References