A simple implantation of coaxial reservoir system placement for hepatic arterial infusion chemotherapy: With no fixation of the catheter tip technique - preliminary result

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Purpose

Background & purpose

Hepatic arterial infusion chemotherapy (HAIC) using an implanting catheter and port system (i.e., reservoir) plays an important role in the treatment of unresectable malignant tumor.

In 1982, Arai et al. (1) first reported a radiologic method of implanting a 5F catheter system. The catheter tip was simply inserted into the common or proper hepatic artery. However, as major complications, frequent catheter dislocation and hepatic arterial occlusion were reported in 8.8 % and 6.8-22.3 % with this original method (2, 3). The catheter implantation method of unfixed catheter tip in the hepatic artery could potentially cause catheter dislocation. The swinging tip mechanically stimulated the inner lumen and anticancer agents infused from the catheter tip were toxic to the endothelium of the artery, which may cause arterial occlusion.

In 1996, Takeuchi and Arai et al. (4) reported a modified version of the original method, a fixed catheter tip method (original FCT method), in which they fixed a 5F catheter tip to a vessel with the use of embolizing coils and infusing anticancer agents through a side hole of the catheter in order to overcome these complications. The side hole was made in the 5F catheter and the catheter tip was placed in the gastroduodenal artery. The position of the side hole was adjusted to the ostium of the common hepatic artery.

Embolization microcoils were inserted into the gastroduodenal artery to fix the catheter tip and occlude the gastroduodenal artery. Fixation of the catheter tip and creation of the side hole decreased catheter dislocation and hepatic arterial occlusion to a rate of 3.0-5.4 % and 6.3-12.2 % (4-6).

However, this FCT method was technically difficult and complex. It sometimes took much skill to introduce the 5F implantation catheter into the hepatic artery using a 0.035 inch guide wire and to control the microcatheter via the side hole of the implantation catheter to fix itself.

In 2001, Irie (7) modified the original FCT method to enable an easier method by implanting a tapered microcatheter (50-cm proximal shaft; 5F in diameter and 20-cm distal shaft; 2.7F in diameter). This catheter was able to be advanced into the gastroduodenal artery easier using a 0.016 inch guide wire, which could be advanced far into the branch of the gastroduodenal artery. Furthermore, with the tapered microcatheter, there was less disturbance of the hepatic arterial flow that lead to prevention of hepatic arterial occlusion at a rate of 3.4-5 % (7, 8). Thereafter, this modified FCT method has become most favorable in Japan.
In 2007, Hamada et al. (9) developed a new reservoir system that included a coaxial catheter. They coaxially implanted a 2.9F microcatheter through a 5F catheter, of which a side hole was created and the tip was fixed as well as the original FCT method. They used this system for patients with stenotic, tortuous, or small hepatic arteries.

Meanwhile, it is not rare to withdraw reservoir systems in cases of infection or hematoma around the system and for other reasons. The necessity of withdrawal of reservoir systems has been reported at a rate of 9.7 - 22.0 % in various studies (10-12). In most cases, even with the fixed catheter tip technique, withdrawal may be easy, but make the operators fatiguing and increasing the tension level because there is always the risk of coil migration. On the other hand, when the catheter tip is not fixed to the target vessel, withdrawal is always easy, safe and requires a short period of time. It is enough only to take the catheter out.

The ideal reservoir system can be considered to be one where the implanting and withdrawal are technically easy and safe, and there is less occurrence of long term complications such as catheter dislocation and hepatic arterial occlusion.

We then hypothesized that if a thin caliber catheter made a side hole can be simply implanted into hepatic artery, the ideal system mentioned above might be achievable.

Therefore, since 2004, we have simply implanted a microcatheter with a side hole through a 5F catheter into the hepatic artery using the percutaneous transfemoral approach. The side hole of the microcatheter was positioned at the common or proper hepatic artery without fixation of the catheter tip.

The purpose of this study is to describe our simple method and preliminary results.
Methods and Materials

Materials and Methods

Patients

Between February 2004 and November 2008, 210 patients (160 men and 50 women, age range 23-84 years; mean age 63 years) with unresectable liver neoplasms underwent placement of percutaneous implantable coaxial catheter reservoir systems with no fixation of the catheter tip for HAIC in our institution. One hundred and seventy-nine patients had primary liver neoplasm including hepatocellular carcinoma (HCC) \( n = 173 \), cholangiocellular carcinoma \( n = 5 \) and hepatic hemangiosarcoma \( n = 1 \). The remaining 31 patients had liver metastases from colorectal cancer \( n = 16 \), pancreatic cancer \( n = 9 \), duodenal carcinoid \( n = 1 \), breast cancer \( n = 4 \) and esophageal cancer \( n = 1 \). A total 242 coaxial catheter reservoir implantation systems were attempted for these 210 patients including 2 systems for separated hepatic arteries in 6 patients, 2 systems for re-implantation after withdrawal of the previous system in 22 patients and 3 systems for third implantation after two withdrawals of the previous systems in 2 patients.

Device

A tapered microcatheter (Sniper; Clinical Supply, Gifu, Japan), 2.9F outer diameter of the proximal shaft and 2.5F of the distal shaft, was used as an implanted catheter. It is made of polyamide elastomer and has a polymer coating on its surface. A 5F heparin-coated catheter (Frosty catheter; Clinical Supply) was used as a "parent catheter" to support the microcatheter, thereby creating the coaxial system (Fig 1 on page 8). The microcatheter and 5F catheter were connected to the port (THERDICA Port 3Fr; Clinical Supply). Details of these devices and how to connect the catheters to the port are described in a previous report (Fig 2 on page 8) (9).

Coaxial Reservoir Implantation Technique

All procedures were performed by two or three experienced interventional radiologists at our interventional radiology unit after obtaining written informed consent from patients or their families. Multiphase computed tomography (CT) imaging had been obtained before all procedures.

Ipsilateral common femoral artery was punctured using the Seldinger technique and a 4F vascular sheath (S-one sheath 4Fr; Clinical Supply) was inserted. Then celiac and superior mesenteric arteriography was performed through the 4F catheter (Selecon PA catheter; Clinical Supply) to assess hepatic vascular anatomy. The locations and vascular invasions of liver neoplasms were examined by a combination of CT during hepatic arteriography (CTHA) and CT during arterial portography (CTAP).
Before implanting the catheter, the right gastric artery and gastroduodenal artery were routinely embolized with microcoils (Tornado & Nester; Cook Medical Inc., Bloomington, IN, USA) to prevent influx of anticancer agents into the gastrointestinal system using a microcatheter (Microferrt-18; William Cook Europe, Bjaeverskov, Denmark) through the 4F catheter. If the hepatic arteries were separated, we usually implanted the catheter into the target artery that was the main vessels of tumors without unifying the blood flow redistribution to the entire liver with coil embolization (i.e., if a replaced right hepatic artery from a superior mesenteric artery was a target artery, the implanting catheter was into itself). We performed transcatheter arterial chemoembolization (TACE) for non-target or extrahepatic feeding arteries except the most favorable for catheter placement instead of non-unifying.

Thereafter, coaxial reservoir catheter was implanted according to the following method: a 5F heparin-coated catheter was then introduced in exchange for the 4F catheter over a guide wire and the tip of the 5F catheter was placed into the celiac or superior mesenteric artery as a parent catheter to support the microcatheter. Before placement of the microcatheter, a side hole was manually created at a point of 0.5-7.0 cm (0.5-3.0 cm at an early stage of this study and 3.5-7.0 cm at a later stage was favorably chosen) from the end of the microcatheter with surgical scissors (Fig 1 on page 8). The distance was determined by pulling a 0.018 inched guide wire back from a planed position of the tip to that of the side hole inside the microcatheter used for embolization or TACE on an X-ray beforehand. The tip of the implanting microcatheter was advanced over the 0.018 inched guide wire. The side hole of the microcatheter was adjusted at the common (CHA) or proper hepatic artery (PHA) with no fixation of the catheter tip. Following this, the implanting microcatheter through the 5F catheter was connected to the port. Finally, the port was implanted into the subcutaneous pocket in the lower abdomen wall above the puncture site (Fig 3 on page 9).

All procedures of diagnostic angiography, embolic procedures, TACE, withdrawal of prior implanted catheter, and catheter placement were performed together in a single session in all patients.

**HAIC and Follow up**

HAIC performed by gastroenterologists was initiated within one week after reservoir implantation. The infusion protocols were decided for each malignancy. Commonly, the protocols for patients with HCC were intra-arterial low-dose cisplatin and 5-fluorouracil (5-FU), intra-arterial 5-FU plus interferon (IFN) combination therapy or intra-arterial low-dose cisplatin and 5-FU plus systemic gemcitabine combination therapy (GEMFP). Details of these protocols were described in our previous report (13). The protocol for patients with metastatic tumor from colorectal cancer was weekly high dose FU.

Before the initiation of all HAIC cycles and when some trouble of the reservoir system were suspected, angiography and CT arteriography via the reservoir system was typically
obtained to confirm that the catheter and hepatic artery were patent and the target tumors were perfused adequately. The reservoir system was flushed and filled with 10 ml of heparin solution (100 IU/ml) at the end of each chemotherapy session.

**Evaluation**

Follow up period was defined from the date of reservoir system implantation until the date of occurrence of any events such as patient death, discontinuation of HAIC for reservoir trouble, or until the termination of HAIC.

Outcome was evaluated by success rate of placement of the reservoir system, time required for the reservoir system implantation from arrival to leaving the interventional unit and complications related to the reservoir system during the follow up period.

Specific complications related to this coaxial reservoir system consisted of incidence of dislocation of the implanted catheter, occlusion or severe stenosis of the hepatic artery and occlusion of the reservoir system. Non-specific complications included hematoma and infection around the system, catheter infection, etc.

Dislocation of the catheter was categorized into two groups as non acceptable dislocation (ND) and acceptable dislocation (AD); ND lead lead to discontinuation of HAIC, while AD was meant to be continuation of HAIC.

Occlusion of the reservoir system was defined as catheter or port occlusion and port destruction

We categorized our reservoir implantation methods into three types in the aspects of the hepatic vascular anatomy and the catheter tip positions (Fig 4 on page 10) and statistically analyzed incidence of dislocation of the implanted catheter and occlusion or severe stenosis of the hepatic artery among these three types using the Mann-Whitney Test (U-test). Type A was defined as where both the catheter tip and the side hole were positioned at CHA or PHA. Type B was defined as where the catheter tip and the side hole were positioned at the right or left hepatic artery and at CHA or PHA, respectively. Type C was defined as where both the catheter tip and the side hole were positioned at the replaced right hepatic artery (RHA) arising from the superior mesenteric artery (SMA) or abdominal aorta. The distance between the catheter tip and the side hole in Type B was typically longer than that of Type A and C.

A statistically significant difference was considered to be a P-value < 0.05 in all the above analyses.
Fig. 0: Fig. 1 Entire coaxial catheter system A. Photograph shows the entire coaxial catheter system consisting of a microcatheter, a 5F catheter and a port. B. Photograph shows that a physiologic saline injected from a port flows out from a side hole (arrow) of the microcatheter under the 5F catheter.

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Fig. 0: Fig. 2 How to connect the catheters to the port 1. The trailing ends of the 2.9F microcatheter and 5F catheter are cut off. 2. The trailing end of the 5F catheter over the 2.9F microcatheter is cut off along a line created around the surface of the 5F catheter with a knife to appear the 2.9F microcatheter through the 5F catheter. 3. The 2.9F microcatheter is connected to the port connector. 4. The 5F catheter is then slid over the 2.9F microcatheter and connected to the port connector. 5. A plastic cap is used to cover both catheters and reinforce the joint.

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Fig. 0: Fig. 3 63-year-man with HCC and portal vein tumor thrombus A. Celiac arteriogram obtained before catheter placement shows no anatomical variations in the hepatic arteries and visualization of tumor stain (arrows). B. After placement of the coaxial catheter reservoir system, a plain X ray shows the coaxial implanted catheter (arrow) and microcoil (arrowheads) for embolization of the gastroduodenal, right gastric and accessory left gastric arteries. C. Arteriogram obtained via the implanted catheter shows good distribution to the entire liver from a side hole (arrow) and cessation of flow in the gastroduodenal, right gastric and accessory left gastric arteries.

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Fig. 0: Fig. 4 Categorizations of reservoir implantation methods Type A is defined as where both the catheter tip and side hole are positioned at the common hepatic artery or proper hepatic artery. Type B is defined as where the catheter tip and the side hole are positioned at the right or left hepatic artery and at common hepatic artery or proper hepatic artery, respectively. Type C is defined as where the catheter tip and the side hole are positioned at the replaced right hepatic artery arising from the superior mesenteric artery or abdominal aorta. Arrows and arrowheads show catheter tips and side holes.

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Results

Result

Success rate of placement of reservoir system

The catheter-port system was successfully implanted using the coaxial catheter placement method without fixation in 241 systems (99.6 %) out of a total 242 systems. All these successful cases experienced no major complications related to the procedure. In one failed case, it was difficult to insert the indwelling microcatheter into the replaced RHA after the withdrawing previous implanted 5F catheter due to severe stenosis of origin of the replaced RHA arising from the SMA.

Time required for the reservoir system implantation

Total time required for the procedure was 119 ± 28 minutes (mean ± SD), ranged from 58 to 185 minutes, including CTAP/CTHA in 162 sessions, coil embolization in 163 sessions, TACE in 72 sessions and withdrawal of the previous reservoir system in 19 sessions.

Follow up period and type of implantation method

Seven patients with 7 systems were lost to follow up because they had a plan of HAIC in other institutions. Two hundred and thirty-four systems in 203 patients were able to be assessed for complications during the follow-up period. Median follow up period was 124.5 ± 230.7 days, ranged from 7 to 1393 days.

Total 234 systems were performed using Type A (166 sessions), Type B (53 sessions) and Type C (15 sessions) of the implantation method of coaxial catheter reservoir systems. In the three groups, median follow-up periods were 139.5 ± 229.6 (ranged from 7 to 1393 day) in Type A, 102.0 ± 207.2 days (ranged from 15 to 950 days) in Type B and 56.0 ± 353.5 days (ranged from 13 to 1344 days) in Type C.

Complications

The complications of all reservoir systems are summarized in Table 1 on page 14.

The results of the type of catheter implantation relevant to occlusion or severe stenosis of the hepatic artery and non-acceptable dislocation are shown in Table 2 on page 14.

Catheter dislocation
The incidence of dislocation of the implanted catheter was 17.1% (40/234 sessions) consisting of 6.8% (16 sessions) in ND and 10.3% (24 sessions) in AD in all sessions during the follow-up periods. The incidence of ND were 8.4% (14/166 sessions) in Type A, 3.8% (2/53 sessions) in Type B and 0% (0/15 sessions) in Type C, respectively. The rate of ND in Type A tended to be higher than in Types B and C, although there were statistically no significant differences among these of three types.

**Occlusion or severe stenosis of the hepatic artery**

The incidence of occlusion or severe stenosis of the hepatic artery was 4.7% (11/234 sessions). They were 4.2% (7/166 sessions) in Type A, 5.7% (3/53 sessions) in Type B, 6.7% (1/15 sessions) in Type C, respectively. There were statistically no significant differences among these three types.

**Oclusion of the reservoir system**

The incidence of occlusion or severe stenosis of the hepatic artery was 4.3% (10/234 sessions) including the incidence of a broken port which was 1.3% (3/234 sessions).

**Non-specific complications**

Non-specific complications during the follow-up period were as follows: hematoma and/or infection related to the implanted port and/or puncture site (17 sessions; 7.3%), catheter infection (5 sessions; 2.1%), side effect of chemotherapy (5 sessions; 2.1%), leak of anticancer agent around the implanted port (2 sessions; 0.9%), and intermittent claudication due to severe stenosis of the external iliac artery (1 session; 0.4%)

**Withdrawal and re-implantation**

Fifty-five systems underwent the withdrawal procedure due to complication (44 sessions) or accomplishment of predestinate HAIC (7 sessions). Twenty six of the 44 systems underwent re-implantation for resumption of HAIC.
**Table 1** Summary of complications in 234 reservoir systems

<table>
<thead>
<tr>
<th>Complications</th>
<th>Incidence rate (%)</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Specific complications related to reservoir systems</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Catheter dislocation</td>
<td>17.1</td>
<td>40</td>
</tr>
<tr>
<td>Acceptable dislocation (AD)</td>
<td>10.3</td>
<td>24</td>
</tr>
<tr>
<td>Non-acceptable dislocation (ND)</td>
<td>6.8</td>
<td>16</td>
</tr>
<tr>
<td>Occlusion or severe stenosis of hepatic artery</td>
<td>4.7</td>
<td>11</td>
</tr>
<tr>
<td>Reservoir system occlusion</td>
<td>4.3</td>
<td>10</td>
</tr>
<tr>
<td><strong>Non-specific complications</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hematoma and/or infection related to the implanted port and/or puncture site</td>
<td>7.3</td>
<td>17</td>
</tr>
<tr>
<td>Catheter infection</td>
<td>2.1</td>
<td>5</td>
</tr>
<tr>
<td>Side effect of chemotherapy</td>
<td>2.1</td>
<td>5</td>
</tr>
<tr>
<td>Leak of the anti-cancer agent around the implanted port</td>
<td>0.9</td>
<td>2</td>
</tr>
<tr>
<td>Intermittent claudication due to severe stenosis of external iliac artery</td>
<td>0.4</td>
<td>1</td>
</tr>
</tbody>
</table>

**Fig. 0**: Specific complications in reservoir implantation methods

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## Table 2: Specific complications in reservoir implantation methods

<table>
<thead>
<tr>
<th>Type</th>
<th>Number of Systems</th>
<th>Mean observation period** (days)</th>
<th>Artery Occlusion or severe stenosis***</th>
<th>Non acceptable dislocation****</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>166</td>
<td>139.5 ± 229.6 (7-1393)</td>
<td>7 (4.2 %)</td>
<td>14 (6.4 %)</td>
</tr>
<tr>
<td>B</td>
<td>53</td>
<td>102.0 ± 207.2 (15-950)</td>
<td>3 (5.7 %)</td>
<td>2 (3.8 %)</td>
</tr>
<tr>
<td>C</td>
<td>15</td>
<td>56 ± 353.5 (13-1344)</td>
<td>1 (6.7 %)</td>
<td>0 (0 %)</td>
</tr>
<tr>
<td>Total</td>
<td>234</td>
<td>124.5 ± 230.7 (7-1393)</td>
<td>11 (4.7 %)</td>
<td>16 (6.8 %)</td>
</tr>
</tbody>
</table>

*Types in reservoir implantation methods is shown in Fig. 4.  
**Mean ± SD and range in parentheses.  
***, **** They are statistically no significant differences among three types.

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**Fig. 0: Summary of complications in 234 reservoir systems**

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Conclusion

This simple method had a technically high success rate. Overall, the incidence of catheter dislocation using this method was a little higher than that of the catheter tip fixation method and the rates of other complications were almost equal compared to recent reports. However, the incidence of catheter dislocation in Types B and C were lower than that of Type A and acceptable compared to recent reports. Due to the ease of implanting and withdrawing this system, this method and Types B and C in particular, may have the potential to become an accepted method for interventional radiology procedures.
References

Reference


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