Original Article

# The comparison of different drip cholangiography: a randomised trial

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**Background:** This study investigated the advantages and disadvantages of contrast media administration by gravity drip and manual push injection during cholangiography.

**Methods:** A total of 100 patients who presented to the Department of Hepatobiliary Surgery, General Hospital of Ningxia Medical University, for a cholangiography between June 2019 to June 2020 were enrolled in this study. Patients were randomly divided into 2 treatment groups. One group of patients with manual injection of contrast (the N group, n=50), received the contrast agent via the traditional manual injection method whereby the doctor injects 50 mL of prepared contrast agent into the right side of the patient while continuously observing the effects on the bile duct. The other group of patients with gravity drip administration of contrast media (the O group, n=50), received the contrast agent via gravity drip at a rate of 80 drops per minute, and both clinicians and radiologists monitored the entire cholangiography process from a safe distance. Patients were followed up and angiographic satisfaction was assessed after two weeks.

**Results:** All 100 patients completed cholangiography without allergic reaction to the contrast medium. In the traditional injection group (N group), nine patients experienced upper abdominal discomfort with nausea, abdominal pain, chills, high fever, and other symptoms, and residual gallstones were observed in 12 patients. In patients in the gravity drip group (O group), four patients felt upper abdominal discomfort accompanied by nausea, abdominal pain, chills, high fever, and other symptoms, with residual gallstones detected in six patients.

**Conclusions:** Patients who underwent gravity drip cholangiography had significantly reduced adverse reactions compared to patients who underwent traditional manual infusion cholangiography. Furthermore, gravity drip cholangiography resulted in clearer images and reduced X-ray exposure for medical staff. Thus, increased implementation of gravity drip cholangiography in the clinical setting should be considered.

**Trial Registration:** Chinese Clinical Trial Registry ChiCTR1800018202.

**Keywords:** Cholangiography; manual infusion; gravity drip

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## Introduction

Interventional radiology (IVR) is a relatively new field which uses modern X-ray diagnostic methods combined with puncture technology to place catheters into the body to facilitate non-surgical treatments, identify lesion sites, and obtain histological, bacteriological, physiological, and biochemical data (1,2). Since IVR is a simple operation that is associated with limited trauma and quick recovery, many intractable diseases can be treated using this method (3). Due to this, IVR has developed exponentially in recent years and together with advances in bioengineering, interventional therapy is now widely applied in most medical disciplines including cardiology, hepatobiliary surgery, urology, gastroenterology, orthopedics, brain surgery, vascular surgery, anesthesiology, trauma, and pediatrics. At present, there are more than 400 types of radioactive interventional procedures used clinically. Unfortunately, with the increased application of IVR, the risk of radiation exposure to medical staff also escalates (4-7).

Endoscopic retrograde cholangiopancreatography (ERCP) and related technologies have become indispensable means for the diagnosis and treatment of biliary and pancreatic diseases (8). To reduce the incidence of complications such as acute cholangitis and acute pancreatitis after ERCP, bile properties should be monitored. Endoscopic nasobiliary drainage (ENBD) is an external bile drainage method commonly used for the treatment of acute cholangitis (9). A slender plastic tube is inserted into bile duct through the duodenal papilla under endoscopy, and the other end leads out from the nostril through the duodenum, stomach, esophagus, pharynx, etc., and is fixed. ENBD can effectively prevent bile mud or residual stones from being lodged in common channels, ensuring smooth drainage of the bile duct and reducing the pressure in the bile duct after ERCP. Furthermore, ENBD minimizes the risk of contrast media and bile entering the pancreatic duct (10). At the same time, routine transnasal cholangiography before extubation can be used to diagnose complications after ERCP and any changes in bile ducts inside and outside liver. This facilitates the detection of residual bile duct stones, biliary strictures, and deformities, and the allows the assessment of duodenal papillary muscle function. This imaging data is important for guiding subsequent clinical management of the patient (11). However, cholangiography is hampered by the prolonged radiation exposure to medical staff. In addition, it is difficult to manually control the speed and pressure of injecting the contrast media and this is often associated with adverse reactions such as abdominal pain, chills, high fever, nausea and vomiting, and in severe cases can cause cholangitis (12).

This study examined the advantages and disadvantages associated with two methods of contrast media administration in patients undergoing cholangiography, namely, the gravity drip method and the traditional manual push injection method.

We present the following article in accordance with the CONSORT reporting checklist (available at https://dx.doi.org/10.21037/apm-21-2661).

## Methods

### *General information*

In total, 100 patients with indwelling ENBD after choledocholithiasis, who were managed in our department between June 2019 and June 2020, were enrolled in this study. The patients were randomly and two-parallel divided into two groups and were blinded to the treatments. One group (the N group; n=50) underwent cholangiography with manual injection of contrast media while the other group (the O group; n=50) underwent gravity drip administration of contrast media which the allocation ratio was 1:1. The trial was immediately terminated in the event of severe pancreatitis and/or bleeding or perforation after biliary surgery. In the O group, there were 39 males and 11 females with an average age of 37.42±4.33 years (range, 27–57 years). There were 36 males and 14 females in the N group, with an average age of 38.26±5.16 years (range, 26–58 years). The basic clinical data of the two groups of patients were comparable (P>0.05). All procedures performed in this study involving human participants were in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by Ethics Committee of General Hospital of Ningxia Medical University (No. 2018251).

 


**Figure 1** The cholangiography procedure using the traditional injection method and the gravity drip method for administration of contrast agent. This image is published with the patient/participant's consent.

### *Inclusion criteria*

Patients were included in this study if they satisfied the following inclusion criteria: (I) patients aged over 18 years; (II) patients with a confirmed diagnosis of choledocholithiasis undergoing ERCP; (III) patients who underwent mini-middle incision of the papillary sphincter during the operation; (IV) patients in whom the ENBD was retained after the operation; and (V) patients who agreed to participate in this study and signed the informed consent form.

### *Exclusion criteria*

Patients were excluded from the study if: (I) they presented with biliary duodenal fistula; (II) the diameter of bile duct exceeds 2 cm; (III) they were allergic to iodine contrast medium; (IV) they presented with mental disorders or were pregnant or lactating; and (V) they were unwilling to participate or unable to sign the informed consent form.

### *Experimental methods*

#### Preparation prior to radiography

Prior to the procedure, the purpose of the examination was explained to the patients and a detailed medical history was obtained, including a history of iodine allergy, history of nausea, vomiting, abdominal distention, abdominal pain, and fever in the preceding 3 days. The imaging data of the bile duct obtained after ERCP was examined. The contrast agent, consisting of 50 mL 0.9% normal saline and 50 mL 30% iodophor, was prepared.

#### Cholangiography procedure

The contrast agent for the cholangiography was administered by 2 different methods, namely, the traditional injection method and the gravity drip method.

For the traditional injection method, a 60 mL syringe was used to manually administer 50 mL contrast agent to the right side of the patient and the speed was about 3.0–3.5 mL/s. The effects on the bile duct were continuously monitored.

For the gravity drip method, an infusion set was hung on an infusion stand placed 50 cm away from the patient. The nipple of the infusion set was connected to the Ruhr locking connector of the nasobiliary duct. The patient was placed in a supine position with his head low and feet high. Fluoroscopy was conducted to evaluate whether the biliary tract overlapped with the spine. If there was overlap, a slope pad was placed to the right, at 15–20°, to avoid interference with the spine. The regulator of the infusion set was then opened and the contrast medium was infused into the bile duct at a rate of 80 drops per minute. After angiography, the infusion set was removed and the nasobiliary duct was connected with the drainage bag (*Figure 1*).

### *Observation indexes*

The angiographic results and angiographic satisfaction in

 

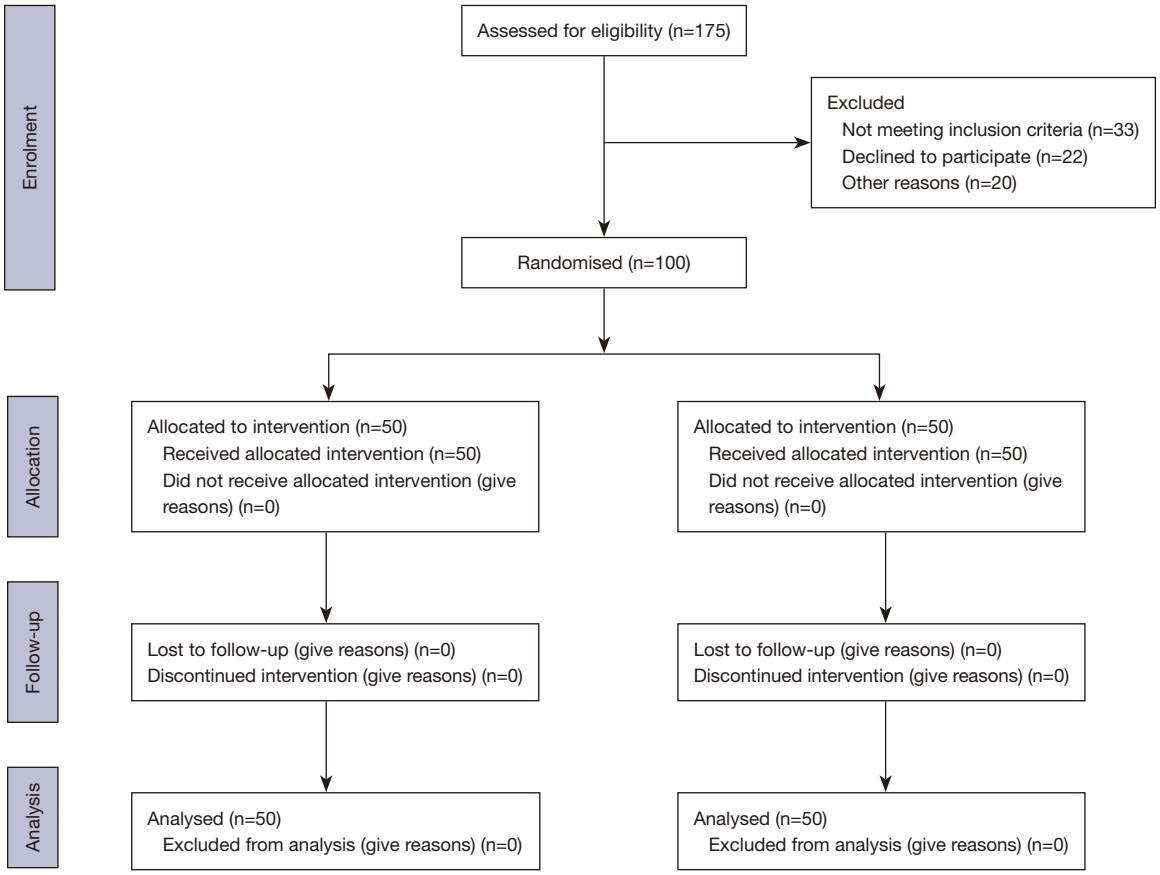


**Figure 2** A flow diagram showing the patient selection process.

the two groups were assessed and compared, which was the primary endpoints.

Any adverse reactions after angiography, including abdominal pain, chills, fever, jaundice, and residual stones, were documented and which was secondary endpoints.

### *Statistical analysis*

Statistical analyses were performed using the SPSS statistical software version 19.0. $P<0.01$ was considered statistically significant. For classified variables, data are expressed as numerical counts and percentages, and the $c^2$ test and analysis of variance was conducted.

## Results

### *Participant selection*

There were 175 eligible patients for this study. A total of 33 patients were excluded based on the inclusion and exclusion criteria. Another 22 patients declined to participate, and 20 patients were excluded for other reasons. Finally, 100 patients with choledocholithiasis were enrolled in this study. These patients were randomly allocated into the N group receiving traditional injection of contrast agent (n=50) and the O group receiving gravity drip infusion of contrast agent (n=50) (*Figures 2*,*3*).

### *The baseline patient demographic and clinical characteristics*

There was no significant difference in the basic demographic and clinical characteristics between patients in the N group and patients in the O group (*Table 1*).

### *Adverse reactions post-cholangiography*

A total of 9 patients in the traditional injection group (N group) experienced upper abdominal discomfort with

 

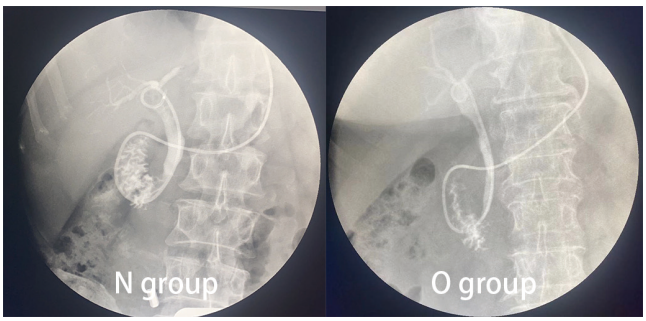


**Figure 3** Representative images of cholangiography by gravity drip and manual injection.

**Table 1** The baseline patient demographic and clinical characteristics

| Characteristic | N group | O group | P value |
|---|---|---|---|
| Gender | 50 | 50 | 0.644 |
| Male | 36 (72.00%) | 39 (78.00%) | |
| Female | 142 (28.00%) | 11 (22.00%) | |
| Age (years) | 38.26±5.16 | 37.42±4.33 | 0.225 |
| Obesity | | | 0.795 |
| Yes | 10 (20.00%) | 8 (16.00%) | |
| No | 40 (80.00%) | 42 (84.00%) | |
| History of pancreatitis | | | >0.999 |
| Yes | 12 (24.00%) | 13 (26.00%) | |
| No | 38 (76.00%) | 37 (74.00%) | |
| History of biliary duct stones | | | 0.833 |
| Yes | 16 (32.00%) | 18 (36.00%) | |
| No | 34 (68.00%) | 32 (64.00%) | |

Data are shown as n (%) or mean ± standard deviation. N group represents patients who were administered contrast agent via the traditional injection method; O group represents patients who were administered contrast agent via the gravity drip method.

nausea, abdominal pain, chills, high fever, and other symptoms, and residual gallstones were detected in 12 patients (*Table 2*). A total of 4 patients in the gravity drip group (O group) experienced upper abdominal discomfort accompanied by nausea, abdominal pain, chills, high fever, and other symptoms (P<0.05; *Table 2*). Residual gallstones were found in 12 patients in the N group and 6 patients in the O group (P<0.05; *Table 2*).

**Table 2** Adverse reactions post-cholangiography

| Group | Abdominalgia | Chills | Fever | Jaundice | Calculus |
|---|---|---|---|---|---|
| N | 3/50 | 3/50 | 2/50 | 1/50 | 6/50 |
| O | 2/50 | 1/50 | 1/50 | 1/50 | 12/50 |
| P value | | 0.0362 | | | 0.0217 |

N group represents patients who were administered contrast agent via the traditional injection method; O group represents patients who were administered contrast agent via the gravity drip method.

**Table 3** Angiographic satisfaction at 2 weeks post-procedure

| Group | Very satisfied | Satisfied | Generally satisfied | Not satisfied |
|---|---|---|---|---|
| N | 22/50 | 12/50 | 9/50 | 7/50 |
| O | 32/50 | 15/50 | 2/50 | 1/50 |
| P value | 0.0372 | 0.0647 | 0.0263 | 0.0187 |

N group represents patients who were administered contrast agent via the traditional injection method; O group represents patients who were administered contrast agent via the gravity drip method.

### *Angiographic satisfaction between two groups*

A follow-up was performed at 2 weeks post-procedure and the angiographic satisfaction was assessed (*Table 3*). In the traditional injection group (N group), 22 patients were very satisfied with the angiography, 12 were satisfied, 9 were generally satisfied, and 7 were dissatisfied. In the gravity drip group (O group), 32 patients were very satisfied with angiography (P<0.05), 15 were satisfied (P>0.05), 2 were generally satisfied (P<0.05), and 1 was dissatisfied (P<0.05).

## Discussion

ERCP and related technologies have become indispensable means for the diagnosis and treatment of biliary and pancreatic diseases. However, there is a risk of acute cholangitis and acute pancreatitis after ERCP. ENBD is particularly important after ERCPs for monitoring bile properties and to assess the presence of residual stones. However, radiography can have serious side effects on both patients and clinicians. Therefore, a new method of cholangiography is urgently needed.

While IVR has its benefits, the radiation exposure of patients and medical staff is of concern, as has been

 

detailed in the 2000 report of UNSCEAR (United Nations Scientific Committee on the Effects of Atomic Radiation). Radiation can cause changes in DNA structure, DNA metabolism, and inhibition of chromosome synthesis (13). At high doses, it can cause chromosome aberration, changes in cell membrane structure, function, and cell morphology, and can also block cell division and lead to cell death. Furthermore, it has mutagenic, carcinogenic, and radiation genetic effects. Therefore, interventional diagnosis and treatment procedures may eventually be restricted (14) unless protective measures can be implemented. Current guidelines for IVR include the following: (I) interventional staff should constantly improve their operation skills so as to proceed efficiently and accurately to minimize exposure time; (II) avoid repeated exposure; (III) control the dose of the original emission and shorten the irradiation time; and (IV) reduce the number of operators, with the remaining staff protected behind a shield.

The traditional method involves bolus injection of the contrast agent manually via a push syringe. The doctor draws a 30% meglumine diatrizoate solution into a 50 mL syringe, stands beside the patient, and injects the radiography agent by hand. This method has certain disadvantages. First, the injection of the contrast agent is only guided by the doctor's experience and the biliary tract pressure. This is difficult to control and can result in excessively high pressure in the biliary tract. When the pressure in the bile duct is greater than 2.94 kPa, bacteria, toxins, and contrast media may enter the systemic circulation through capillaries or the lymphatic system, causing sepsis and even septic shock. Abdominal pain, chills, fever, chest tightness, and vomiting have been reported in clinics. The adverse reaction rate of patients with traditional radiography is 27% (15). Second, during the process of manual drug injection, it may appear that gas is entering the bile duct. Third, the bedside physician is exposed to radiation which may result in radioactive damage. Furthermore, the clinician cannot observe the whole radiography process from the bedside, and this is not conducive to the diagnosis of difficult cases.

Conversely, the gravity drip cholangiography method has certain advantages. First, the contrast agent enters the biliary tract evenly by gravity drip, which avoids the risk of sudden excessive pressure in the biliary tract. Second, patients can control the drip rate through the infusion regulator and control the biliary tract pressure such that it is within their tolerable range. This allows individualized radiography, which reduces the adverse reactions of radiography. Third, both clinicians and radiologists can monitor the contrast media entering the biliary tract in real time and direct the patient to change their body position so that the branches of the biliary tract can be filled completely. This facilitates the diagnosis of residual stones and other conditions, thereby improving the accuracy of the diagnosis. Furthermore, the gravity drip method negates the need to expose medical personnel to radiation.

In this study, 9 patients in the traditional injection method group (N group) experienced upper abdominal discomfort with nausea, abdominal pain, chills, high fever, and other symptoms, with residual gallstones found in 12 patients. However, in the gravity drip group (O group), only 4 patients experienced upper abdominal discomfort, accompanied by nausea, abdominal pain, chills, high fever, and other symptoms, with residual gallstones detected in 6 patients. Moreover, the patient satisfaction associated with the gravity infusion method was higher than that of the traditional manual injection method. The limitation of this study is that the number of cases included in the study is limited. If more cases can be included in the study, the value of the study will be more obvious.

In summary, the report demonstrated that gravity drip radiography is simple and easy to operate and can effectively reduce imaging complications, protect medical staff from radiation damage, enhance the quality of radiography, and improve the accuracy of diagnosis.

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## Footnote

*Reporting Checklist:* The authors have completed the CONSORT reporting checklist. Available at https://dx.doi.org/10.21037/apm-21-2661

*Trial Protocol:* Available at https://dx.doi.org/10.21037/apm-21-2661

*Data Sharing Statement:* Available at https://dx.doi.org/10.21037/apm-21-2661

 

*Conflicts of Interest:* All authors have completed the ICMJE uniform disclosure form (available at https://dx.doi.org/10.21037/apm-21-2661). The authors have no conflicts of interest to declare.

*Ethical Statement:* The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was approved by Ethics Committee of General Hospital of Ningxia Medical University (No. 2018251) and written informed consent was obtained from all patients. All procedures performed in this study involving human participants were in accordance with the Declaration of Helsinki (as revised in 2013).



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