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A Novel Remote-Controlled Injection Device for T-Tube Cholangiography: A Feasibility Study in Canines

Authors' Contribution:

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Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
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Background: The purpose of this study was to develop a remote-controlled injection device for T-tube cholangiography to avoid occupational exposure.


Material/Methods: The remote-controlled injection device has 3 major components: an injection pump, a pressure sensor, and a wireless remote-control panel. The feasibility and effectiveness of this device for T-tube cholangiography was evaluated in *ex vivo* porcine livers using a laparoscopic training platform and in *in vivo* canine experiments.

Results: The contrast dye was successfully injected into the biliary tracts of the *ex vivo* porcine liver and canines by the designed device. The X-ray images clearly showed the anatomical structure of the bile ducts. No obvious adverse reaction was observed in the dogs during or after the procedure. All steps were controlled remotely, avoiding ionizing radiation exposure to the surgeons.

Conclusions: This novel remote-controlled injection device for T-tube cholangiography can assist operators in completing cholangiography remotely and protecting them from occupational exposure.

MeSH Keywords: **Cholangiography • Equipment Design • Remote Sensing Technology**

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Background

Biliary diseases are the leading causes of hepatobiliary morbidity across the world. The incidence of gallstone diseases in some developed countries ranges from 10% to 20% [1,2]. Many postoperative hepatobiliary diseases require biliary drainage [3–5], and T-tube is a kind of latex conduit used for biliary diversion in the common bile duct (CBD), and it is reported to reduce intra-biliary pressure and edema, prevent bile leakage, and may facilitate healing. Open surgery with CBD exploration and T-tube drainage are still traditionally performed in many selected patients with cholelithiasis and choledocholithiasis [6]. T-tube cholangiography is performed routinely to observe and evaluate the prognosis before the removal of the T-tube [7]. T-tube cholangiography requires injecting contrast dye into the biliary tract through the T-tube. Because this procedure is performed with X-ray radiation, operators are exposed to ionizing radiation. Although the use of a lead apron provides some protection, a recent investigation [8] showed that a 0.5-mm lead apron blocked just over one-third of the radiation scattered towards the surgeon. Most of the lead aprons were found to provide insufficient protection [9] and increased discomfort and fatigue [10]. Thus, the residual radiation during the procedure could be a threat to clinicians, especially for long-term radiological work.

The purpose of this study was to develop a remote-controlled injection device specifically designed for T-tube cholangiography. The feasibility and effectiveness of this device for T-tube cholangiography was evaluated in an *ex vivo* porcine liver model using a laparoscopic training platform and in *in vivo* canine experiments.

Material and Methods

Device composition

The structure

The device consists of 3 major components: an injection pump, a pressure sensor, and a wireless remote-control panel. The operation terminal consists of the injection pump and the pressure sensor, and the control terminal consists of the wireless remote-control panel. The injection pump replaces the human operator to inject the contrast dye, and the pressure sensor was responsible for perceiving the injection pressure. The wireless remote-control panel was used to set up parameters and command the operation terminal. The structure and program were designed according to the clinical operation requirements, and the schematic diagram and control program codes are shown in Figure 1.

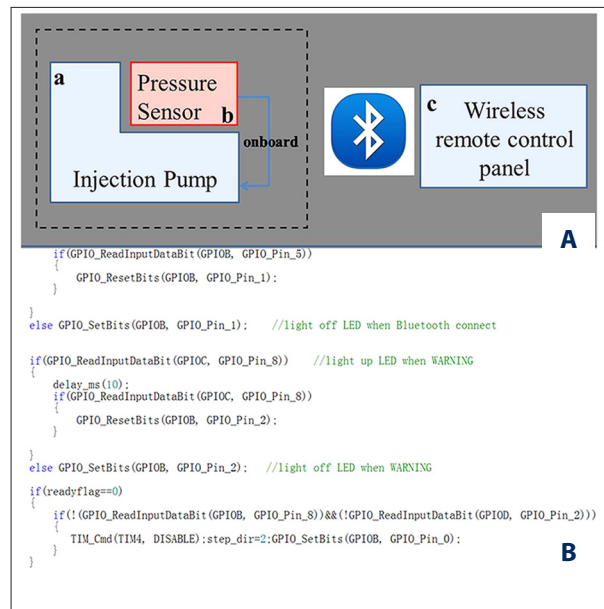


Figure 1. (A) System architecture of the novel device. a: The injection pump; b: The pressure sensor is loaded on the injection pump; c: Wireless remote-control panel. a, b, and c achieved wireless communication through Bluetooth. (B) Partial program codes of the wireless remote-control panel.

Technical parameters

We recorded the range of injection speeds and the key operation points of T-tube cholangiography during the examination process for 20 patients. Then, the mean injection speed and dosage of the contrast dye were calculated as a reference for technical parameters of the device. All patients participating in the experiment signed the informed consent and the study was approved by the hospital Ethics Committee.

Ex vivo and in vivo experiments

Ex vivo test

A laparoscopy training platform [11] was used for the *ex vivo* test and a porcine liver was placed in the platform for the cholangiography model. A 20-Fr T-tube was inserted into the common bile duct and fixed with 1-0 silk. Then, the T-tube was connected to a syringe filled with 40 mL of dilute contrast agent (1: 1), and the syringe was loaded onto the injection pump. After adjusting the position of the C-arm and targeting the liver, the operators left the room and injected the contrast dye through the wireless remote-control panel, and observed the effect of cholangiography and the transmission of wireless signals simultaneously. A general infusion pump (Mindray Benefusion SP5) was used as a controlled test.

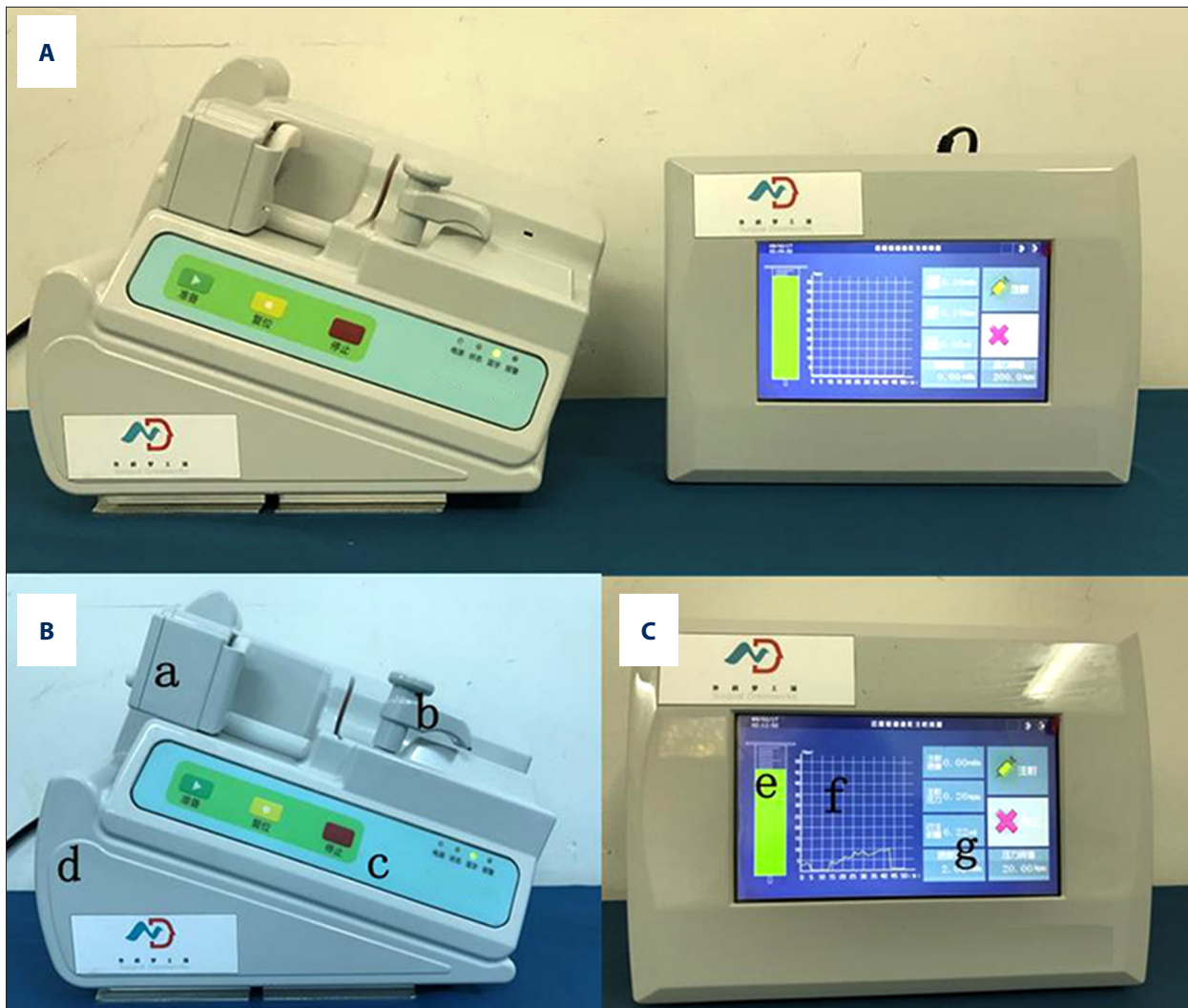


Figure 2. (A) The prototype of the remote-controlled injection device for T-tube cholangiography. (B) The operation terminal: a: The syringe pushing rod contains a pressure sensor; b: The syringe slot; c: The reset buttons and indicator lights; d: The support platform. (C) The control terminal (wireless remote-control panel): e: The injection volume diagram; f: The pressure curve diagram; g: The parameter setting and control buttons.

In vivo experiment in canines

We used 4 male mongrel canines with a mean weight of 15 kg. All canines were fasted before the operation. After anesthesia, a venous access was established through the paw vein. During operation, anesthesia was maintained by intravenous injection of pentobarbital. A median incision of the abdomen was made in each canine, exposing the liver and gallbladder, making a small incision at the bottom of the gallbladder, and removing the bile stored in the gallbladder with an aspirator. Next, a 14-Fr T-tube was inserted into the common bile duct through the cholecystal incision and fixed with 1-0 silk. A small incision was made beside the left costal margin, where the T-tube was placed and fixed on the skin with silk suture. The subsequent operation and observational indicators were the

same as performed in the *ex vivo* test. The same technical parameters (injection speed and pressure threshold) were used to perform T-tube cholangiography, and the injection pressure of each dog was recorded. After the operation, the T-tube was removed, excising the gallbladder and closing the incision with an interrupted absorbable suture. During the process of cholangiography, the radiation doses were measured in different environments by a radiation monitor (FUT FS2011), and the effect of cholangiography on the 4 cases were evaluated by the same experienced doctor.

Follow up

Each dog received postoperative conventional treatment, including the fluid and antibiotics (benzyl penicillin sodium)

Table 1. Data collected of 20 cases from clinical cholangiography. These data were calculated as a reference for technical parameters of the designed device.

No.	Contrast agent dose (mL)	Injection time consuming (S)	Injection volume per second (mL/s)	Injection course per second (mm/s)	T-tube specification (Fr)
1	10	14	0.7	2.45	20
2	15	9	1.7	5.95	20
3	10	5.7	1.75	6.125	20
4	12	4.6	2.6	9.1	20
5	15	11.7	1.28	4.48	16
6	15	10.9	1.38	4.83	8
7	18	21	0.86	3	20
8	20	38	0.53	1.9	20
9	20	20	1	3.5	20
10	20	11	1.8	6.3	20
11	20	18	1.1	3.85	8
12	20	11.5	1.74	6.09	20
13	20	7.6	2.6	9.1	20
14	18	16.2	1.11	3.89	16
15	15	9	1.67	5.83	20
16	15	7.5	2	7	20
17	20	13.8	1.45	5.08	20
18	20	25	0.8	2.8	20
19	20	16.5	1.21	4.24	20
20	18	12	1.5	5.25	20
Mean ±SD	18±3.37	14.15±7.53	1.44±0.55	5.04±1.92	/

necessary to prevent infection. Pethidine (1 mg/kg, bid) was injected for pain control after the dogs recovered from the re-anesthesia for 12 h. All animals were fasted on the first post-operative day, and then water and normal diet were supplied and gradually increased. In addition to the indicators mentioned above, adverse events were recorded to assess the device.

Results

The characteristic and technical parameters of the device

Table 1 shows the data collected from clinical cholangiography. The injection speed ranged from 0.53 ml/s to 2.6 ml/s at the mean of 1.44 ml/s, while the injection volume was 10–20 ml (mean volume was 18 ml). These data were calculated as a basic reference for technical parameters of the device. The size of

the injection pump was approximately 30×23×13.2 cm and the wireless remote-control panel was 22.2×16×8.8 cm (length, width, and height, respectively) (Figure 2). The syringe slot of the injection pump could be inserted into a 50 mL disposable syringe and was designed on an incline so that the bubbles in the T-tube would be pumped back and float to the end of the syringe. The syringe pushing rod was equipped with a pressure sensor which can perceive the pressure fluctuation and transmit the real-time data to the wireless remote-control panel. The control panel can set technical parameters such as injection speed and pressure threshold and display the real-time injection volume and injection pressure data. When the injection pressure was above the preset pressure threshold, the operation terminal would stop injecting immediately. The wireless communication was achieved via Bluetooth, and the PowerClass2 standard transmission distance was 10 meters.

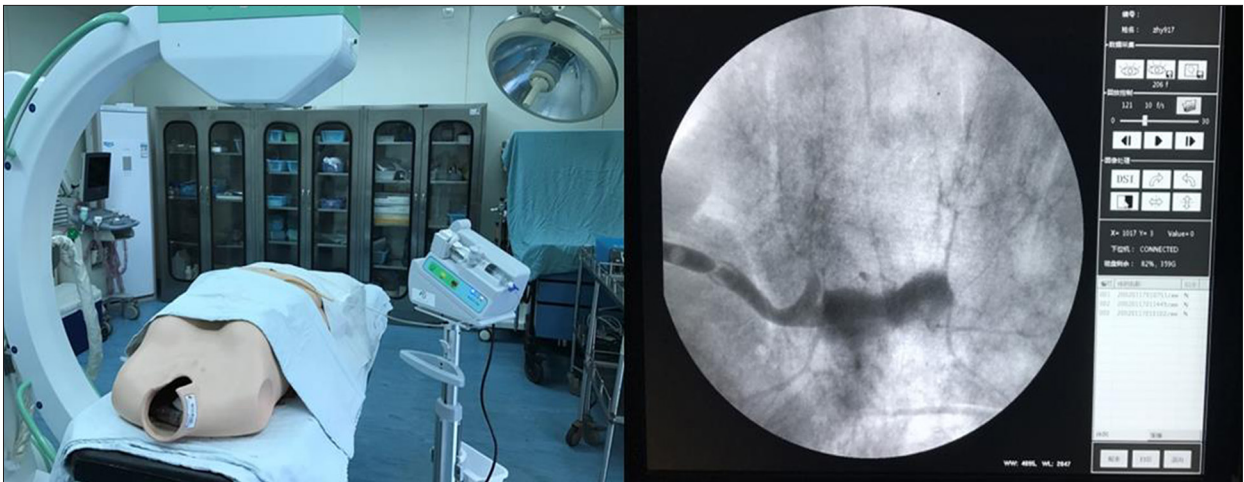


Figure 3. The *ex vivo* test performed by the novel remote-controlled injection device. The bile duct of the porcine liver was clearly displayed.

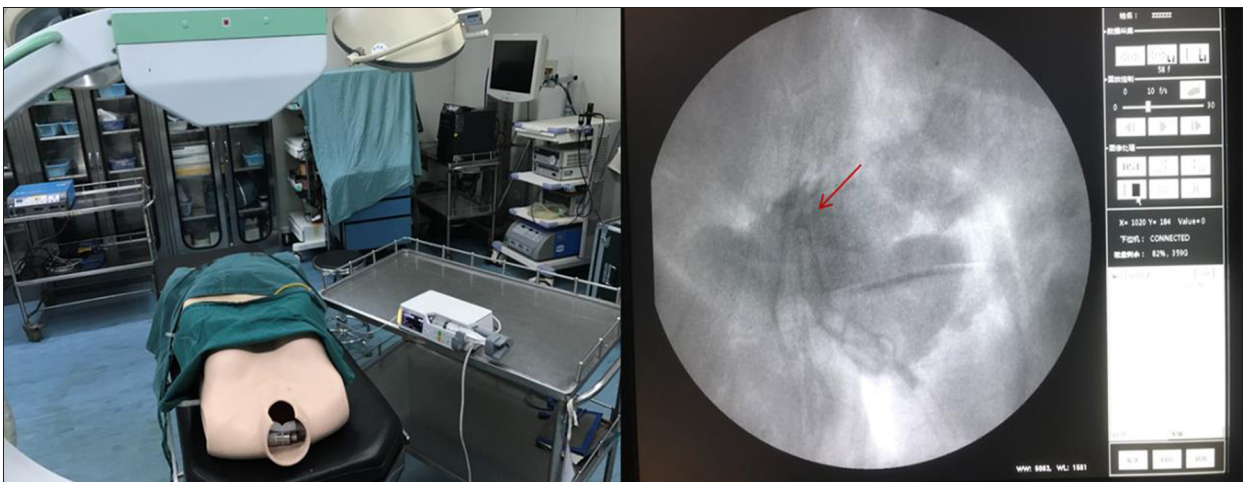


Figure 4. The *ex vivo* test performed by the ordinary infusion pump. The image was blurred and unclear.

The feasibility of the device was verified in a porcine liver

The designed device successfully completed T-tube cholangiography through remote control, and the biliary system was clearly displayed on the computer screen (Figure 3). The ionizing radiation environment did not interfere with the remote wireless transmission and it remained stable. However, the image of the cholangiography for the ordinary infusion pump was blurred and unclear (Figure 4).

The device can be successfully applied in canine experiments without obvious adverse reactions

According to the data collected from clinical T-tube cholangiography (Table 1), the injection speed of the canine experiments was set to 1 mL/s and the injection volume was (11.08 ± 2.07) mL. The pressure threshold was set to 20 kPa and the average injection pressure was about (13.43 ± 2.55) kPa.

T-tube cholangiography under remote control using the novel remote-controlled injection device was successfully performed in all 4 cases (Table 2) and the operator was no longer exposed to ionizing radiation. With the contrast dye injected, the biliary system was gradually developed on the screen and the anatomic structure of the bile ducts was clearly exhibited (Figure 5). All of the experimental dogs gradually recovered from anesthesia 2–6 h after surgery. The activity and diet gradually were increased to normal, and no adverse reactions associated with T-tube cholangiography were observed.

Discussion

T-tube cholangiography is the most commonly used method for the observation of the biliary tract after hepatobiliary surgery [3–7,12]. Despite the use of protective equipment such as lead aprons [13], clinicians in our hospital who perform T-tube

Table 2. Summary of the animal experiments.

No.	Whether successfully completed cholangiography remotely	Time required for applying the device (min)	Contrast agent dose (mL)	Injection volume per second (mL/s)	Radiation dose to the operator/lead shield/dog (uSv)	injection pressure (Kp)	The effect of cholangiography
1	Yes	5'08	12.3	1	0.00/0.13/2.11	12.2	5
2	Yes	4'47	8.9	1	0.00/0.08/1.82	10.6	4
3	Yes	4'13	9.8	1	0.00/0.07/1.73	14.5	4
4	Yes	3'31	13.3	1	0.00/0.10/2.03	16.4	5

Radiation dose to the operator/lead shield/dog represented radiation dose in observation room, lead aprons protection area in operating room, and non-protection area in operating room, respectively. The effect of cholangiography was divided into 5 grades (5 to 1 represents: excellent, good, fair, bad, poor), evaluated by an experienced doctor.

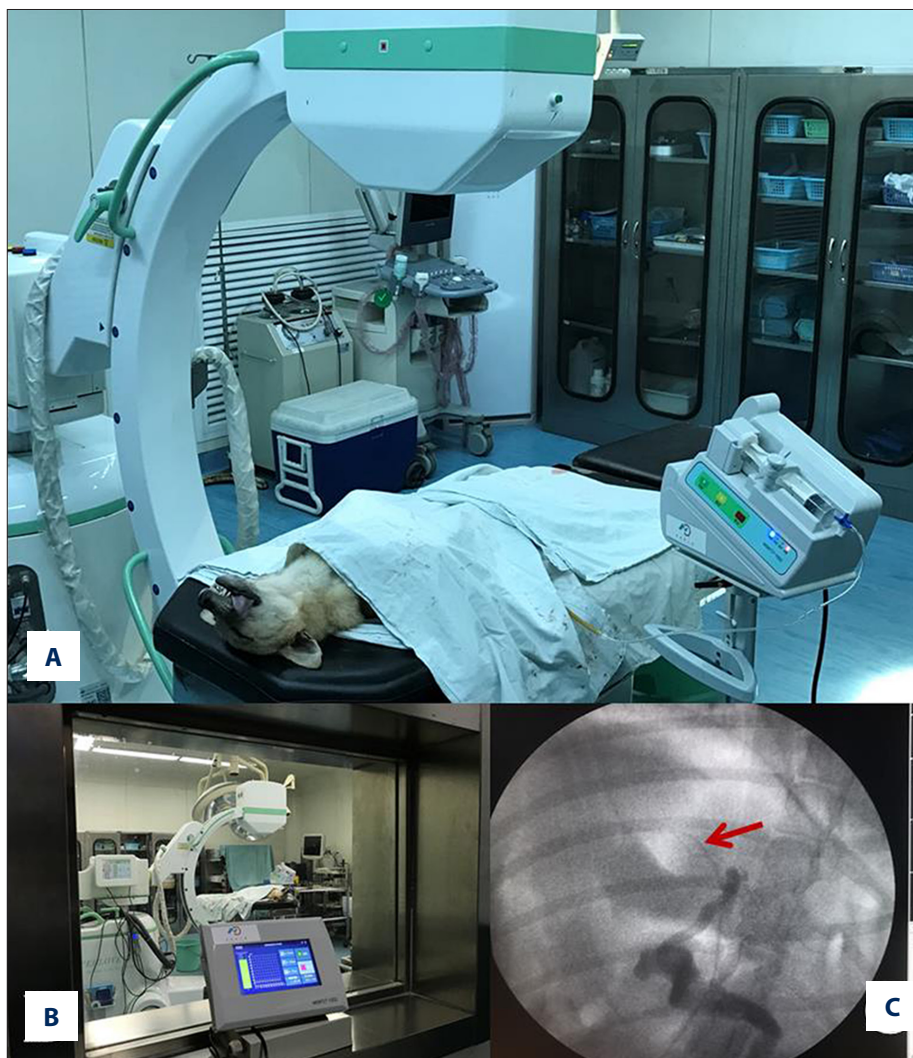


Figure 5. The canine experiments performed by the novel remote-controlled injection device. (A) The operation terminal connected to the T-tube. (B) The operator used the control terminal in the observation room. (C) The extrahepatic bile duct can be clearly displayed and the arrow showed the small branches of the intrahepatic bile duct.

cholangiography usually receive about 0.21 mSv of radiation per month. In this study, we developed a remote-controlled injection device specifically designed for T-tube cholangiography. The injection of the contrast dye for T-tube cholangiography was controlled wirelessly through a Bluetooth-based technique. The operators did not need to be exposed to X-ray radiation during the procedure. Thus, this novel device effectively protected the operators against radiation exposure without wearing heavy lead aprons. The feasibility and effectiveness of this device for T-tube cholangiography was confirmed using an *ex vivo* porcine liver and *in vivo* canine experiments. To the best of our knowledge, this remote-controlled injection device is the first one specifically designed for cholangiography.

Due to a direct anatomic communication between biliary canaliculi and liver sinusoids, an increase in biliary pressure [14] can initiate reflux from the biliary system into the bloodstream [15]. If bacteria are present in the bile, cholangiovenous or cholangiolymphatic reflux of bacteria may lead to systemic bacteremia [16]. During traditional T-tube cholangiography, however, the intraductal pressure is not monitored and the injection pressure is controlled manually. Consequently, fever and chills are not infrequent following T-tube cholangiography [17]. When designing this device, we incorporated a pressure sensor. During T-tube cholangiography, the real-time injection pressure and the exact feedback data are exhibited on the touch panel of the control terminal. In addition, the operator can set a pressure threshold through some calculations and clinical experience according to patients' preoperative indicators, including ultrasound imaging and bilirubin levels. If the injection pressure is above the preset pressure threshold, the operation terminal will stop injecting to ensure patient safety.

Inadvertently injected air bubbles can resemble calculi in cholangiograms. However, the withdrawal of bubbles, while maintaining the safety of the injection system, can be challenging. In this remote-controlled injection device, the syringe slot in the injection pump is placed in an inclined position. Our *ex vivo* and *in vivo* feasibility studies demonstrate that this design can facilitate bubble removal before injecting the contrast dye.

Although a variety of injection devices have been clinically used to reduce manpower needed to finish the injection operation [18,19], none of them has been reported to be used for T-tube cholangiography. For example, the high-pressure injector used in enhanced CT (Tennessee XD2003, Ulrich GmbH and Co., KG) cannot be applied in cholangiography because of the high injection speed of the device. The lowest injection speed in some of high-pressure injectors is 3 mL/s, which is higher than the maximum speed (2.6 mL/s) we observed in traditional T-tube cholangiography. A high injection speed may increase the biliary pressure and cause cholangiovenous re-gurgitation [15,20]. Our present experiment also shows that an ordinary infusion pump is unsuitable for cholangiography because it generates blurred and unclear images due to its lower injection speed (max speed: 2000 mL/h).

Conclusions

We have successfully developed a novel remote-controlled injection device to perform T-tube cholangiography. This device may assist operators in completing cholangiography remotely and protecting them from occupational radiation exposure. Future studies will aim at gaining regulatory approval and conducting clinical trials.

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Conflict of interest

None.

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