

Efficacy and Safety of Gravity Dependent and Hand-Held 'Push' Injection Method of Contrast Cholangiography: Validation of a Pilot Study, A Single Centre RCT

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Abstract

Background and Objectives: Direct cholangiography (DC) involves introducing contrast media into biliary system. Choice of technique, push injection (PIC) or gravity drip (GDC), affects the risk of complications post-procedure. A pilot study conducted at our centre suggested, major adverse reactions were significantly more common in PIC than GDC. We conducted a randomised controlled trial, to validate the results of the pilot study, by comparing two techniques for adverse reactions and efficacy. Also, we describe a, modified GDC technique which is economic and safe.

Methods: A randomized controlled trial was conducted from November 2023 to May 2024 including all patients requiring DC. Patients with active cholangitis or complete biliary obstruction were excluded. After randomisation in two groups i.e., PIC and GDC, participants were observed within 24hrs post procedure, for adverse reactions and efficacy of cholangiography. (CTRI/2023/10/059252).

Results: 64 eligible candidates were randomised into two groups- GDC and PIC groups (32 in each group). 6 had displaced tube and 4 in GDC group had long standing blocked tubes requiring PIC. Procedure failure rate of GDC was 12.9% (v/s 0%, p=0.001). As per protocol analysis, minor adverse effects were seen in 11.1% in GDC group and 41.9% in PIC group (p=0.009). While major adverse effects were seen in 7.4% in GDC group and 35.5% in PIC group (p=0.011). This significant difference in translated into a higher overall treatment cost (3.7% v/s 25.8% p=0.029). Both techniques were equally efficacious.

Conclusion: We advocate routine use of modified gravity dependent technique of contrast media administration for its safety.

Keywords

Cholangiography, gravity-dependent, push-injection.