



Utility of Bio-Degradable Bile Duct Stents Following Bile Leaks and Pre-Operative Stone Clearance: International, Prospective, Multi-Centre, Observational Cohort Study

Suresh Vasan Venkatachalapathy¹, Martin W James¹, Deepak Joshi², Gavin Johnson³, Simon Philpotts³, Manu Nayar⁴, Matthew Huggett⁵, Danny Cheriyan⁶, Christopher Clarke¹, Damilola Olajide¹, Aloysious D Aravinthan¹, Guruprasad P Aithal¹

Abstract

Introduction: Endoscopic retrograde cholangio-pancreatography (ERCP) and biliary stenting provides faster resolution of bile leaks post-cholecystectomy, while its use pre-cholecystectomy remains controversial. In both scenarios, patients frequently need repeat procedures for removal of stent. Novel biodegradable stents may prevent the need for repeat procedures. We tested the utility of these in a prospective multi-centre observational study.

Methods: Consecutive patients referred for ERCP, either for treatment of bile leaks or removal of bile duct stones (pre-cholecystectomy), were recruited from 6 tertiary centres in the United Kingdom and Ireland between December 2020 and August 2022. The primary objective was to assess the clinical success of biliary drainage with biodegradable stents. The secondary objectives were to assess the technical success, complications, patient discomfort, stent visibility on fluoroscopy, stent degradation, quality of life (QoL) before and after the procedure, and the health economics of these stents.

Results: Sixty-five patients were included. The stent placement was feasible in all patients with a clinical success of 96.8%. Forty-three patients (88%) had complete stent degradation, 2 (4%)-partial degradation, and 4 (8%)-no degradation at day-90. QoL measure improved by 14-fold during 90 day follow up – 17-fold improvement in the bile leak and 13-fold in the bile duct stone cohort. Elimination of repeat procedures would result in a cost saving of £332 per patient for all indications.

Conclusion: Biodegradable stents are associated with excellent clinical success rate and improvement in QoL post- procedure. This is also associated with cost savings to health care providers.

Affiliation:

¹NIHR Nottingham Biomedical Research Centre, Nottingham University Hospitals NHS Trust, and School of Medicine, University of Nottingham, Nottingham, United Kingdom

²Institute of Liver Studies, King's College Hospital NHS Foundation Trust, London, United Kingdom

³University College London Hospitals NHS Foundation Trust – Department of Gastroenterology, London, United Kingdom

⁴Population Health Sciences Institute, Newcastle University & Newcastle Upon Tyne Hospitals NHS foundation Trust, United Kingdom

⁵Leeds Teaching Hospitals NHS Trust – Gastroenterology, Leeds, Leeds, United Kingdom

⁶Department of Gastroenterology, Beaumont Hospital and RCSI, Dublin, Ireland

*Corresponding author:

Suresh Vasan Venkatachalapathy, NIHR Nottingham Biomedical Research Centre, Nottingham University Hospitals NHS Trust, and School of Medicine, University of Nottingham, Nottingham, United Kingdom.

Citation: Suresh Vasan Venkatachalapathy, Martin W James, Deepak Joshi, Gavin Johnson, Simon Philpotts, Manu Nayar, Matthew Huggett, Danny Cheriyan, Christopher Clarke, Damilola Olajide, Aloysious D Aravinthan, Guruprasad P Aithal. Utility of Bio-Degradable Bile Duct Stents Following Bile Leaks and Pre-Operative Stone Clearance: International, Prospective, Multi-Centre, Observational Cohort Study. Journal of Biotechnology and Biomedicine. 8 (2025): 278-286.

Received: December 06, 2025

Accepted: December 09, 2025

Published: August 21, 2025



Introduction

The incidence of post-cholecystectomy bile leak is 0.5–1% [1,2] and 4–7.2% following liver resection [3-5]. Endotherapy of bile leaks with stents is an accepted mode of treatment [1,6,7]. Biliary stenting achieves resolution of the leak therefore, is recommended by the European Society of Gastrointestinal Endoscopy [7]. Among patients with bile duct stones treated with endoscopic sphincterotomy, wide variability exists in the timing of cholecystectomy [8]. COVID-19 pandemic has significantly delayed non-cancer surgeries such as cholecystectomy for gallstones [9]. Around 10% have bile duct stones during cholecystectomy and it is associated with unfavourable outcomes [10,11]. Therefore endoscopists may consider prophylactic biliary stenting in patients following endoscopic clearance of bile duct while awaiting cholecystectomy [12]. A novel biodegradable bile duct stent (Archimedes®, AMG) has been designed to spontaneously biodegrade and this eliminates the need for subsequent stent removal at ERCP. We undertook a multicentre prospective observational cohort study to assess the efficacy of bio-degradable stents.

Materials and Methods

Design

A multicentre, prospective, observational, cohort study was undertaken to assess the clinical effectiveness and utility of biodegradable stents in bile duct drainage in 6 centres across the UK and Republic of Ireland - Nottingham University Hospitals, University College London Hospital, King's College Hospital, Newcastle upon Tyne Hospital, Leeds Teaching Hospital and Beaumont Hospital, Dublin. All consecutive patients referred for ERCP treatment for bile leak and bile duct stones (fit for cholecystectomy) were eligible for inclusion in the study (Flow chart 1).

Primary and secondary objective

The primary objective was to assess the clinical success of biodegradable stents in bile duct drainage. The secondary objectives were to assess the technical success, complications, QoL before and after the procedure and health economic assessment of placing the stent.

Inclusion criteria

All adult patients who had bile leaks (either post cholecystectomy or liver resection) and patients presenting with symptomatic bile duct stones with intact gallbladder who would be considered for cholecystectomy were included in the study.

Exclusion criteria

Patients not fit for cholecystectomy, routine stent exchange, where bile duct stone clearance was not achieved, patients with ECOG 4 (Eastern cooperative oncology group) and female patients who were pregnant were excluded.

Eligible patients willing to participate were consented both for the study and the ERCP procedure on the day of endoscopy. During baseline visit, demographics, and quality of life (QoL; (using EQ-5D-5L) data were collected. The stent size was chosen at the discretion of endoscopist during the procedure. Seven French pushing catheter was used to deploy the stent over wire.

Biodegradable Bile duct stent (Archimedes®, AMG)

The biodegradable stents are polymeric stents manufactured with different mixtures of polydioxanone, poly-ethylene glycol, barium sulphate and lactide-caprolactone-co-trimethylene carbonate depending on the degradation profile of the stent. The helical design allows the bile to flow on the outer extremities of the stent, while supporting the opening of the lumen. The proximal and distal flanges minimize migration and are impregnated with barium to make them radiopaque under X-ray. They have different degradation profiles; fast degrading stents maintains structural integrity for 12 days, medium -25 days and slow degradation-11 weeks. We tested slow degrading stents in this study (Figure 3,4), based on the likely time required for bile leak resolution or interval to cholecystectomy. All patients had sphincterotomy before stent insertion. These are CE marked for the above indications.

In-vitro degradation of Stent:

In-vitro degradation was evaluated in a controlled laboratory setting. The stent was placed in a mock tube and was immersed in Sorensen buffer solution to maintain a pH of 7.4±0.2. The Sorensen buffer solution was flowed continuously. The stent degradation was assessed continuously with video monitoring at day-30, -60, -90, -120, -150, -180 and -190 time points (time lapse video 1).

Stent follow up

After the procedure, patients were followed up for 270 days (on 1, 7, 30, 60, 90, 180, and 270 ±3 days). During these appointments, data on adverse events and QoL were collected. The EQ-5D-5L questionnaire was completed by the patient unless they needed assistance. At day 90±3 days, abdominal X-ray (AXR) was performed to assess the degradation of the stent. A central radiologist blinded to the timing of index ERCP reviewed the AXR at Nottingham. X-rays from other centres were electronically transferred to Nottingham. If there was partial or no degradation, then the AXR was repeated on day 180, 270 and until, there was complete degradation of the stent. Achievement of complete degradation of stent was considered completion of the study (Flow chart 1).

Outcomes

The clinical success of treating bile leaks was defined as resolution of bile leak and removal of external drain. Clinical success for bile duct stones was defined as improvement or

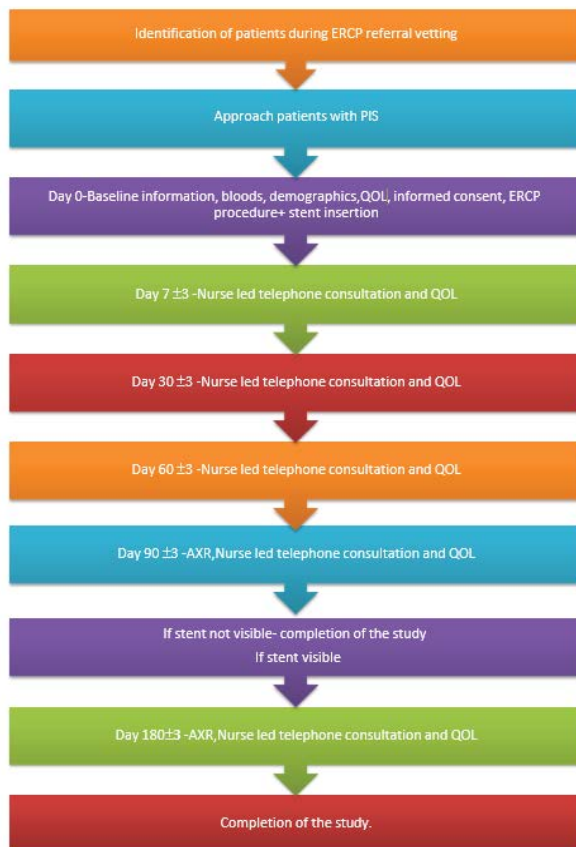


Figure 1: Study Flow Chart.

resolution of symptoms following the procedure. Technical success was defined as successful placement of biodegradable stent into the bile duct. Stent failure was defined as failure to resolve bile leak or readmission with symptoms in case of CBD stones. Stent visibility was defined as clear image of the stent on fluoroscopy after deployment (Figure 4). They were categorised into excellent, good, neutral and poor visibility on fluoroscopy. Stent degradation was defined as complete if <25% of stent was visible in the region of CBD; partial if 25–75% of the stent was visible and no degradation if >75% of the stent was visible [13].

Sample size calculation

With an estimated sample size of 53 patients and the quoted success rate of 77–100% [6, 14-16], we would be able to detect an overall success rate at the lower end of the range of 77% with a precision allowing an estimated 95% confidence interval of 64-88%. If the success rate was at the upper end of the range at 95%, then this would be measured with a precision allowing an estimated 95% confidence interval of 84-99%.

Statistical Analysis

Categorical variables were presented as number with percentages rounded to the nearest integer; continuous

variables were presented as median and interquartile range (IQR). Statistical analyses were performed using GraphPad prism 9 (San Diego, CA). Wilcoxon matched pairs signed rank test was used to compare individual components of QoL at different time points of assessment. A p-value of <0.05 was considered significant.

Health economic analysis

The economic evaluation comprised cost analysis and assessment of QoL. For cost analysis, the direct (hospital-related) costs and indirect (patient-related) costs were compared between a counterfactual current practice plastic stenting [6, 15] and observed biodegradable stenting methods, to derive estimates of cost saving. The sensitivity of cost saving was tested at zero cost of repeated procedures for stent failure. The QoL for each patient, derived from their response to items in EQ-5D-5L questionnaire (Pain/discomfort, mobility, self-care, usual activities, and anxiety/depression), was further used to generate utilities weighted by time factors to derive the quality-adjusted life year (QALY). The QALY provided a measure of how well all the ERCP procedure improved the patients' lives as of each of the post-ERCP procedure inspection days in the year. All analyses were conducted using Microsoft Excel.

Ethical Approval

National Research Ethical Committee and NHS Health Research Authority approval was obtained for the study (REC ID: 285192). Nottingham University Hospitals NHS trust was the sponsor of the study (study ref: 20GA041). This study was registered with clinical trials.gov (NCT04477005) and was adopted as an NIHR portfolio study (CPMS ID: 46829).

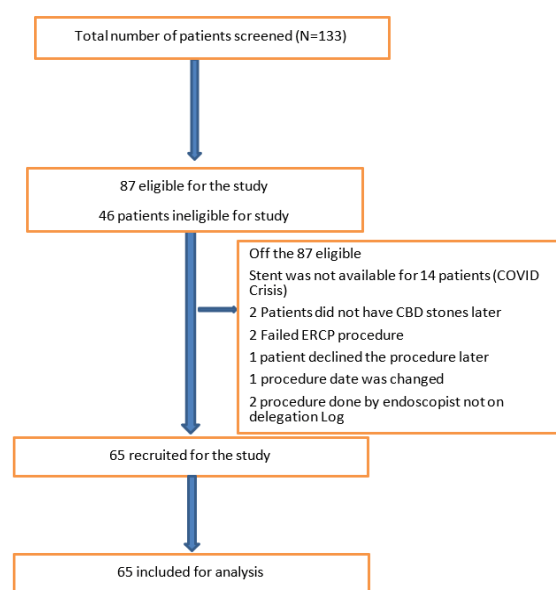


Figure 2: Consort Diagram.

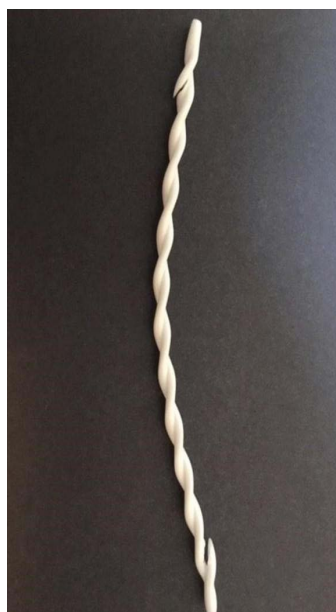


Figure 3: Biodegradable bile duct stent (10Fr, 8cm).



Figure 4: Fluoroscopic image of Stent after insertion.

Results

A total of 133 consecutive patients were screened; of which 65 patients were recruited (figure 2 Consort diagram). Forty (62.5%) patients were female; median age was 67.5 years (IQR 52–73); median ECOGs status was 1 (IQR 1–2). Fifty-five (85%) patients had CBD stones and 9 (14%) had bile leak (8 post-cholecystectomy and 1 liver resection) as the sole indication; one patient (2%) had both post-cholecystectomy bile leak and bile duct stone. Forty-one patients (63%) underwent the procedure under conscious sedation and 24 (37%) under propofol sedation or general anaesthesia (Table 1).

The technical success was 100% and the clinical success was 96.8%. Thirty-five (54%) had 8Fr, while 29 (45%) had 10Fr stents (information not available for one stent). The stent deployment was judged by the endoscopists as easy in 59 (91%) and neutral in 6 (9%—neither easy nor difficult). The visibility of the stent on fluoroscopy was excellent in 46

(71%), good in 13 (20%), neutral in 5 (8%) and poor in one (2%) patient (Table 2).

Table1: Patient demographics.

Patient characteristics	Data
Total number of patients recruited	65
Males Vs Females	25(37.5%) Vs 40 (62.5%)
Ethnicity	Caucasians 57(87%)
	Other 8 (13%)
Age (median, IQR)	67.5 (21)
ECOG (median, IQR)	1(2)
CBD stones	55 (86%)
Sedation Vs GA/propofol sedation	41 (62.5%) Vs 24 (38.5 %)
Pethidine dose (median, IQR)	50 mg (25)
Fentanyl dose (median, IQR)	62.5 mcg (68.75)
Midazolam (median, IQR)	2.5 (2mg)
Rectal NSAID	52 (81%)

Table 2: Procedure Characteristics.

Stent Characteristics	Data
Technical success	100%
Diameter10Fr Vs 8Fr	29(45%) Vs 35 (55%)
Length 8cm Vs 6cm	31 (47%) Vs 34 (53%)
Stent deployment (Easy Vs Neutral)	59 (91%) Vs 6 (9%)
Visibility of stent on fluoroscopy	
Excellent	
Good Neutral Poor	46 (70.31%)
	13 (20.31%)
	5 (7.81%)
	1 (1.56%)
Patient discomfort during the procedure (median,IQR)	1 (0)
Patient discomfort in recovery (median,IQR)	1 (0)
Immediate adverse event	1 (1.56%) mild bleeding

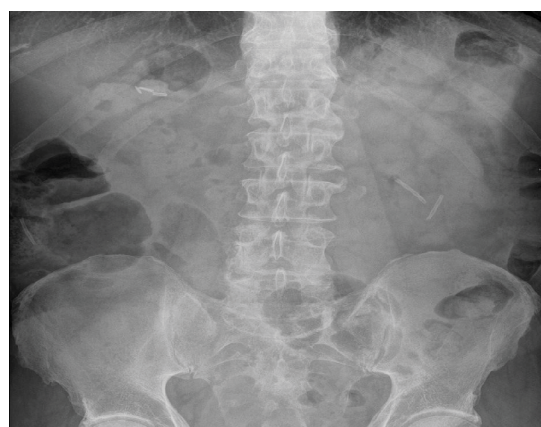


Figure 5: AXR- complete degradation of stent at 90 days.

Stent degradation profile was available in 49 patients at 90 days. Forty-three patients (88%) had complete, 2 (4%) had partial, and 4 (8%) had no degradation at day-90. The 43 patients with complete degradation were discharged from the study at day-90. Of the rest, only 3 attended follow up AXR

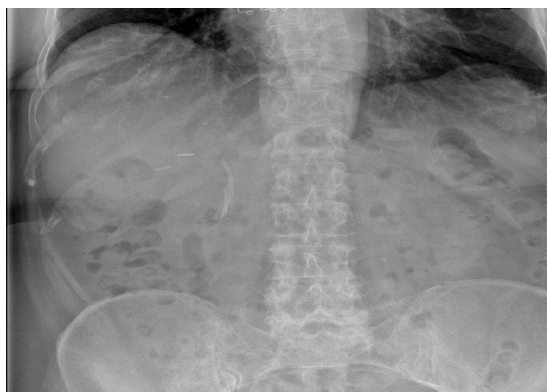


Figure 6: AXR partial degradation of Archimedes BD.



Figure 7: AXR no of Archimedes BD.



Figure 8: AXR Complete degradation at 180 days.

- two achieved complete degradation at day-180 and one patient at day-270. None had symptoms related to 'delayed' degradation. The images of stent after insertion, complete, partial and no degradation are shown in images 4–8.

Quality of life before and after the procedure

The QoL measure at day-90 was about 17 times the value of day-7. The QoL measure day 90 was relatively higher (12%) on average for the bile leak than for bile stone indication. The mean QALY increased progressively during

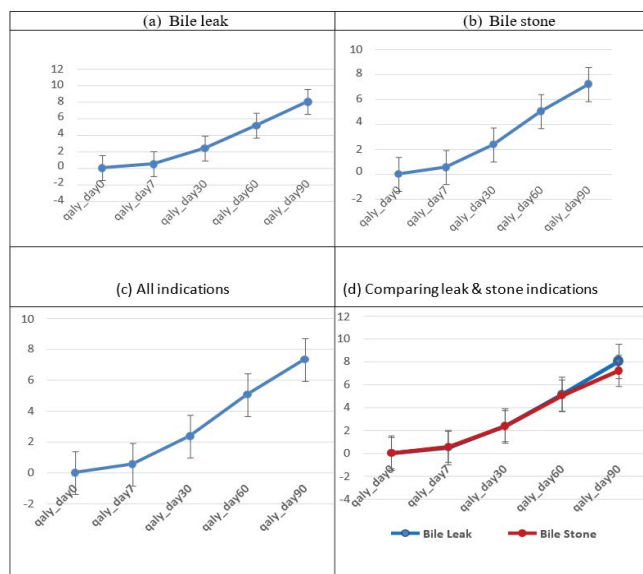


Figure 9: Post ERCP procedure QALYs over follow-up days by indication.

the post-ERCP follow-up inspection days. For the bile leak cohort, the mean QALY increased from 0 at the baseline (day-0) to 0.48 at day-7 ($p=0.0001$; 95%CI 0.28–0.68). The mean QALY increased progressively over the remaining follow-up inspection days reaching 8.03 as at day-90 ($p=0.0001$; 95%CI 5.62–10.43).

For the bile duct stone cohort, the mean QALY increased from 0 at baseline (day-0) to 0.55 at day-7 ($p=0.0001$; 95%CI 0.49–0.61). The mean QALY also increased progressively over the remaining follow-up inspection days reaching 7.20 at day-90 ($p=0.0001$; 95%CI 6.22–8.17).

The result for the entire cohort showed a similar pattern. The mean QALY increased progressively over the follow-up inspection days reaching 7.32 at day-90 ($p=0.0001$; 95%CI 6.44–8.20; Figure 9).

On examining individual components of EQ-5D-5L questionnaire (i.e., pain, mobility, self-care, usual activities, anxiety and depression), there was significant improvement in the pain and anxiety/depression scores. The mean pain score reduced following the procedure and was sustained to day-90 (2.469 Vs 1.67, $p<0.0001$; 95%CI 1.41–1.93). There was an

increase in the mean anxiety score (1.95 Vs 1.26, $p < 0.0001$; 95%CI 1.07–1.46).

Cost saving

Procedure cost was highly sensitive to the comorbidity status of patients. An additional comorbidity score increased procedure cost by £292. The adverse events and clinical success rate were comparable to the existing plastic stents. Complete elimination of repeat procedures could save the NHS an additional £332/patient for both indications; £222/patient for bile leak indication. Allowing for spontaneous plastic stent migration; on assumption that a repeat procedure was needed to remove the plastic stents in 90% of cases, hospitals would save £2,185/patient by placing biodegradable stent for both the indications. In this study, the estimated cost saving was £11,356 and £128,473 for bile leak and bile duct stone, respectively.

Complications

There were 9 procedure-related adverse events in the study: one (2%) bleeding (Mallory Weiss tear), 2 (3%) pancreatitis, 1 (2%) cholecystitis, 2 (3%) stent failures and 3 (5%) stent migrations. The stent failures occurred in bile leak indication - one patient already had plastic stent, which was converted to biodegradable stent, and the biodegradable stent failed to resolve the bile leak and hence a metal stent was placed. The bile leak resolved between day-30 and 60 after metal stent placement. The second patient was treated with metal stent and the bile leak resolved quickly after the metal stent placement. One patient with cholecystitis was treated with early cholecystectomy. There was no mortality during the follow-up period.

Table 3: Complications.

Adverse event	Number of patients
Bleeding	1 (1.56%) (Mallory Weiss tear)
Pancreatitis	2 (3.12%)
Cholecystitis	1 (1.56%)
Stent migration	3 (5%)
Stent failure (bile leak)	2 (3.12%)

Discussion

This is the first international, multi-centre prospective observational study assessing the utility of biodegradable stent. There were no technical challenges in placing biodegradable stents. The stent could be advanced over a guidewire with a 7Fr pushing catheter, with fluoroscopic visibility of the stent reported as either excellent or good in 91% of patients. A prospective study on 34 patients previously reported similar outcomes [13]. The overall clinical success

rate was 97% [17]. The helical design of the stent allowed bile to drain along the side of the stent rather than through the stent. This allows biliary drainage even when the stent loses its tensile strength because of degradation and breaks down in fragments (Image 6). This correlate well with the *in-vitro* degradation. This study demonstrates that the biodegradable stent is equivalent to conventional stent but with the added advantage of not needing a repeat procedure.

The stent degradation was assessed centrally by a radiologist blinded to the patient details and time of follow up on day-90, 180 and 270 post-procedure. At day-90, there was complete degradation in 88% and partial degradation in 4% of patients. In this study, we followed them up with AXRs until there was complete degradation. The *in-vivo* degradation was slightly quicker compared to the *in-vitro* degradation done in parallel in the laboratory. This is the first multi-centre study that demonstrates how the stent degrades *in-vivo* during follow-up. As the stent degrades, It loses its tensile strength, breaks down in to fragments and then either migrate into the small bowel if they are small or remain in bile duct if the fragments are large (Figure 5-7). This was similar to the *in-vitro* degradation. They did not dissolve and disappear as it was anticipated before the study.

This study demonstrates sustained significantly improved QALY following ERCP and biodegradable stent insertion. This is the first study to demonstrate sustained improvement in QALY up to 90 days for both indications examined. The QALY provides a measure of the value that patients placed on their health status during post-ERCP follow-up. During post-ERCP follow-up (day-90 follow-up), patients QoL increased by 17-fold in the bile leak cohort compared to 13-fold in the bile stone cohort. Irrespective of the indication, QoL measure improved 14-fold during the follow-up period. The QoL measure was relatively higher (~12%) for the bile leak than for bile stone indication. Bile leaks are a significant post-operative sequela and are associated with significant morbidity, increased 1-year mortality and reduced long term QoL [18, 19]. There was stent failure in 2 patients, defined as failure to resolve bile leak. Both the patients required fully covered metal stents to resolve the bile leak following laparoscopic cholecystectomy in one and after liver resection in the other. The reported failure rate for plastic stents following hepato-biliary surgery is 23% and 12% following cholecystectomy [20-23]. Most studies showed that a proportion of patients needed sequential plastic stent placement to resolve the bile leak. Covered metal stents have higher success rate for bile leak following hepato-biliary surgery [24]. There were no stent-related adverse events and the ERCP-related adverse events were comparable to the existing literature [25]. As these stents are straight and the flare of the flanges are minimal they are prone to migration.

The stent migration occurred in all three patients who had sphincteroplasty. Hence, placing these stents may not be helpful following sphincteroplasty.

The estimated cost savings was £1,136/patient and £2,379/patient for bile leak and bile duct stones, respectively. For a tertiary centre performing 400 procedures, assuming 50% would be suitable for biodegradable stent insertion and keeping stent failure at approx. 4%, this could save the NHS about £22,712, £8,816 and £6,828 for bile leak, bile duct stones, and all indications, respectively, other things being equal. For a smaller hospital performing around 100 procedures, this could save about £11,356, £4,408, and £3,414, respectively.

This study was conducted during COVID-19 crisis hence access to surgery for benign indications such as cholecystectomy was severely limited. The “CONTACT” study reported that there was significant reduction in access to cancer surgery and palliative chemotherapy during COVID crisis [26]. At least in the UK, this seems to continue even after COVID because of the long backlog caused by cancellation of benign surgery. If the interval between ERCP and cholecystectomy is longer, then placing a biodegradable stent may be helpful for the patients. The single arm observational nature of the study is an important limitation of this study. This could have led to selection bias and increased intervention effect. However, the multicentre design of this study would have minimised this. As it is a single arm study, we were unable to differentiate the effect of stent from ERCP procedure itself on the QALY of patients following procedure.

In conclusion, this international multi-centre prospective observational study demonstrates that biodegradable bile duct stents are safe, associated with high clinical success rate and significant improvement in the QALY of patients following procedure.

Acknowledgements

The authors are grateful to Samantha Warburton, Sian Parkes, Violeta Anuskievic and Rachelle Boxhall for support with data collection, recruitment and training of staff for the study.

Author Contribution

Suresh Vasan Venkatachalapathy: Chief investigator, Conceptualisation, design, Recruitment, drafting of manuscript

Martin W James: PI for Nottingham, Recruitment, review of manuscript.

Deepak Joshi: PI for Kings hospital, Recruitment, review of manuscript

Gavin Johnson: PI for UCL London, Recruitment, review of manuscript

Simon Philpotts: Recruitment, review of manuscript.

Manu Nayar: PI for Newcastle, Recruitment, review of manuscript

Danny Cheriyan: PI for Ireland, Recruitment, review of manuscript

Matthew Huggett: PI for Leeds, Recruitment, review of manuscript

Christopher Clarke: Independent radiologist, review of manuscript

Damilola Olajide: Health economic analysis

Aloysious D Aravinthan: Statistical analysis, review of manuscript

Guruprasad P Aithal: Recruitment, review of manuscript.

Ethics Statement

Approval of the research protocol by an Institutional Reviewer Board: National research ethical committee (REC) and NHS health research authority approval: 285192

Registry and the Registration No: Clinical trials.gov number: NCT04477005

NIHR portfolio adoption number

CPMS ID 46829 Informed Consent: Obtained

Animal Studies: N/A

Clinical trials.gov number

NCT04477005

National research ethical committee (REC) and NHS health research authority approval: 285192 NIHR portfolio adoption number: CPMS ID 46829

Funding

This was an investigator led industry funded study: funded by Archimedes, AMG and was adopted in to NIHR portfolio studies (CPMS ID 46829). The study was supported by NIHR Nottingham BRC (NIHR203310).

References

1. Barkun AN, Rezieg M, Mehta SN, et al. Postcholecystectomy biliary leaks in the laparoscopic era: risk factors, presentation, and management. *Gastrointestinal endoscopy* 45 (1997): 277-282.
2. Deziel DJ, Millikan KW, Economou SG, et al.

- Complications of laparoscopic cholecystectomy: a national survey of 4,292 hospitals and an analysis of 77,604 cases 165 (1993): 9-14.
3. Yamashita Y, Hamatsu T, Rikimaru T, et al. Bile leakage after hepatic resection. *Annals of surgery* 233 (2001): 45-50.
 4. Tanaka S, Hirohashi K, Tanaka H, et al. Incidence and management of bile leakage after hepatic resection for malignant hepatic tumors. *Journal of the American College of Surgeons* 195 (2002): 484-489.
 5. Koch M, Garden OJ, Padbury R, et al. Bile leakage after hepatobiliary and pancreatic surgery: a definition and grading of severity by the International Study Group of Liver Surgery. *Surgery* 149 (2011): 680-688.
 6. Kaffes AJ, Hourigan L, De Luca N, et al. Impact of endoscopic intervention in 100 patients with suspected postcholecystectomy bile leak. *Gastrointestinal endoscopy* 61 (2005): 269-275.
 7. Dumonceau J-M, Tringali A, Blero D, et al. Biliary stenting: indications, choice of stents and results: European Society of Gastrointestinal Endoscopy (ESGE) clinical guideline. *Endoscopy* 44 (2012): 277-298.
 8. Mador BD, Nathens AB, Xiong W, et al. Timing of cholecystectomy following endoscopic sphincterotomy: a population-based study. *Surgical endoscopy* 31 (2017): 2977-2985.
 9. Ahmed W, Obeng L, Hegazy A, et al. P138 Delays in cholecystectomy after bile duct clearance: another consequence of Covid-19? : BMJ Publishing Group (2022).
 10. Möller M, Gustafsson U, Rasmussen F, et al. Natural Course vs Interventions to Clear Common Bile Duct Stones: Data From the Swedish Registry for Gallstone Surgery and Endoscopic Retrograde Cholangiopancreatography (GallRiks). *JAMA surgery* 149 (2014): 1008-1013.
 11. Clout M, Blazeby J, Rogers C, et al. Randomised controlled trial to establish the clinical and cost-effectiveness of expectant management versus preoperative imaging with magnetic resonance cholangiopancreatography in patients with symptomatic gallbladder disease undergoing laparoscopic cholecystectomy at low or moderate risk of common bile duct stones (The Sunflower Study): a study protocol. *BMJ Open* 11 (2021): e044281.
 12. Kawabata H, Kawakatsu Y, Yamaguchi K, et al. Prophylactic Biliary Stenting Before Cholecystectomy in Patients With Gallstones and Common Bile Duct Stones. *Gastroenterology Res* 12 (2019): 191-197.
 13. Anderloni A, Fugazza A, Maroni L, et al. New biliary and pancreatic biodegradable stent placement: a single-center, prospective, pilot study (with video). *J Gastrointestinal Endoscopy* (2020).
 14. Chinnery GE, Krige JE, Bornman PC, et al. Endoscopic management of bile leaks after laparoscopic cholecystectomy. *S Afr J Surg* 51 (2013): 116-121.
 15. Dumonceau JM, Tringali A, Papanikolaou IS, et al. Endoscopic biliary stenting: indications, choice of stents, and results: European Society of Gastrointestinal Endoscopy (ESGE) Clinical Guideline - Updated October 2017. *Endoscopy* 50 (2018): 910-930.
 16. Yun SU, Cheon YK, Shim CS, et al. The outcome of endoscopic management of bile leakage after hepatobiliary surgery. *Korean J Intern Med* 32 (2017): 79-84.
 17. Manes G, Paspatis G, Aabakken L, et al. Endoscopic management of common bile duct stones: European Society of Gastrointestinal Endoscopy (ESGE) guideline. *Endoscopy* 51 (2019): 472-491.
 18. Booij KAC, de Reuver PR, van Dieren S, et al. Long-term Impact of Bile Duct Injury on Morbidity, Mortality, Quality of Life, and Work Related Limitations. *Ann Surg* 268 (2018): 143-150.
 19. Fong ZV, Pitt HA, Strasberg SM, et al. Diminished Survival in Patients with Bile Leak and Ductal Injury: Management Strategy and Outcomes. *J Am Coll Surg* 226 (2018): 568-76.e1.
 20. Dechéne A, Jochum C, Fingas C, et al. Endoscopic management is the treatment of choice for bile leaks after liver resection. *Gastrointestinal endoscopy* 80 (2014): 626-33. e1.
 21. Ryan ME, Geenen JE, Lehman GA, et al. Endoscopic intervention for biliary leaks after laparoscopic cholecystectomy: a multicenter review. *Gastrointest Endosc* 47 (1998): 261-266.
 22. Kwon C-I, Gromski MA, Oh H-C, et al. Additional flap on plastic stents for improved antimigration effect in the treatment of post-cholecystectomy bile leak. *Endoscopy International Open* 6 (2018): E489-E94.
 23. Katsinelos P, Kountouras J, Paroutoglou G, et al. A comparative study of 10-Fr vs. 7-Fr straight plastic stents in the treatment of postcholecystectomy bile leak. *Surgical endoscopy* 22 (2008): 101-106.
 24. Mangiavillano B, Luigiano C, Tarantino I, et al. Fully covered, self-expandable metal stents for first-step endoscopic treatment of biliary leaks secondary to hepatobiliary surgery: a retrospective study. *Digestive and Liver Disease* 45 (2013): 430-432.

25. Dumonceau J-M, Kapral C, Aabakken L, et al. ERCP-related adverse events: European Society of Gastrointestinal Endoscopy (ESGE) guideline. *Endoscopy* 52 (2020): 127-149.
26. Hall LA, McKay SC, Halle-Smith J, et al. The impact of the COVID-19 pandemic upon pancreatic cancer treatment (CONTACT Study): a UK national observational cohort study. *British Journal of Cancer* (2023).



This article is an open access article distributed under the terms and conditions of the [Creative Commons Attribution \(CC-BY\) license 4.0](https://creativecommons.org/licenses/by/4.0/)

Citation: Suresh Vasan Venkatachalapathy, Martin W James, Deepak Joshi, Gavin Johnson, Simon Philpotts, Manu Nayar, Matthew Huggett, Danny Cheriyan, Christopher Clarke, Damilola Olajide, Aloysious D Aravinthan, Guruprasad P Aithal. Utility of Bio-Degradable Bile Duct Stents Following Bile Leaks and Pre-Operative Stone Clearance: International, Prospective, Multi-Centre, Observational Cohort Study. *Journal of Biotechnology and Biomedicine*. 8 (2025): 278-286.