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‘One shunt fits all?’: A comparative laboratory study of antibiotic-impregnated shunt catheters with retrospective clinical correlation

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Abstract

Introduction: Several antibiotic-impregnated shunt catheters are commercially available, but direct comparative data on their biochemical and physical characteristics remain limited. Previous observations from our single-centre neurosurgical unit suggested that nominally similar catheter types may be associated with different rates of otherwise unexplained abdominal pain. We therefore conducted a prospective comparative study to investigate potential biochemical and physical differences between commercially available antibiotic-impregnated shunt catheters.

Methods: Ares®, Bactiseal® and XABO® catheters were compared for antibiotic content, rifampicin degradation products, elution characteristics and antimicrobial activity. Antibiotic elution was assessed during continuous saline perfusion at 20 mL/h and 37°C over 8 weeks, while antimicrobial activity against *Staphylococcus epidermidis* was evaluated over 60 days. Catheter dimensions, elastic modulus and surface morphology were assessed using three-dimensional computed tomography, nanoindentation and scanning electron microscopy, respectively. An exploratory retrospective quality-improvement dataset from our single-centre unit was additionally analysed to compare the frequency of otherwise unexplained abdominal pain between catheter types.

Results: The three catheter systems showed product-specific differences in antibiotic content, rifampicin degradation profiles, elution characteristics, antimicrobial activity, dimensions, mechanical properties and surface morphology. XABO® most closely matched the declared antibiotic concentrations and retained the greatest proportion of intact rifampicin, while Ares® demonstrated the highest sustained clindamycin elution. All three catheters retained measurable activity against *Staphylococcus epidermidis* for 60 days, with XABO® showing the largest numerical inhibition zones throughout. In the 395-patient retrospective clinical analysis, otherwise unexplained abdominal pain was recorded in 90/182 patients with Ares® catheters (49.5%) compared with 12/108 patients with Bactiseal® catheters (11.1%). After adjustment for age, sex, primary diagnosis, modified Rankin Scale score and activity level, Ares® remained associated with greater odds of abdominal pain than Bactiseal® (adjusted OR 6.89, 95% CI 2.58–18.43; $p < 0.001$).

Conclusion: Commercially available antibiotic-impregnated shunt catheters showed product-specific biochemical and physical variation, while catheter type was associated with different rates of otherwise unexplained abdominal pain in a retrospective single-centre analysis. These findings are hypothesis-generating and do not establish causality or clinical superiority. Prospective multicentre studies are required to determine whether catheter-specific properties

translate into clinically meaningful differences and should influence individualised shunt selection.

Introduction

The BASICS trial reshaped clinical practice in hydrocephalus surgery, one of the most commonly performed neurosurgical procedures worldwide⁽¹⁾. The trial showed that antibiotic-impregnated shunt catheters reduced the risk of shunt infection more effectively than either standard or silver-impregnated catheters⁽²⁾, with the potential to mitigate the substantial morbidity and mortality associated with these complications. This advantage was particularly relevant to neonates and infants, as younger age had emerged as the strongest predictor of both shunt infection and mechanical ventriculoperitoneal shunt failure^(1, 3). The economic analysis also favoured antibiotic-impregnated shunts within the UK National Health Service, estimating savings of £135,753 for each infection prevented and £56,771 for each additional shunt failure avoided compared with standard catheters⁽²⁾. Taken together, these findings positioned antibiotic-impregnated shunts as the preferred option, offering both superior infection prevention and projected annual cost savings of approximately £1 million. Consequently, antibiotic-impregnated shunts became near-universal in routine practice between 2004 and 2021, with use increasing from 36.9% to 99.2% in paediatric patients and from 20.5% to 96.8% in adults⁽¹⁾.

These developments followed the introduction of antibiotic-impregnated silicone catheters containing clindamycin and rifampicin, initially commercialised as Bactiseal® following the work of Bayston and colleagues⁽⁴⁾. Bactiseal® contains clindamycin (0.15%) and rifampicin (0.054%), which are incorporated within the silicone matrix and released from the catheter surface to inhibit bacterial colonisation⁽⁵⁾.

Several alternative antibiotic-impregnated catheter systems have since become commercially available, including Ares®⁽⁶⁾, XABO®⁽⁷⁾ and DESU®⁽⁸⁾. Although these products use similar antimicrobial strategies, direct comparative data on their antibiotic content, degradation profiles, elution behaviour, dimensions and mechanical characteristics remain limited. Consequently, product selection may vary according to availability, institutional procurement and surgeon preference.

Routine use of antibiotic-impregnated shunts also raised concerns that locally released antibiotics might temporarily suppress bacterial growth in microbiological samples and thereby reduce culture sensitivity in genuinely infected shunts⁽²⁾. Bench studies suggest that this effect is greatest during the earliest period of antibiotic release, when antimicrobial concentrations are highest, and diminishes thereafter⁽⁹⁾. Other reported concerns included a relative increase in Gram-negative infections⁽¹⁰⁾, rifampicin-resistant *Staphylococcus epidermidis*⁽¹¹⁾, allergic reactions, and revisions in patients with clinical features of infection despite negative cultures⁽²⁾. These observations highlight the need to understand not only whether antibiotic-impregnated catheters reduce infection, but also how their release characteristics may influence microbiological diagnosis and resistance patterns⁽¹²⁾.

Antibiotic impregnation did not eliminate the conventional complications of ventriculoperitoneal shunting, including constipation, local tenderness, peritonitis, adhesions, hernia⁽¹³⁾, bowel perforation, pseudocyst formation, infection⁽¹⁴⁾, and pain caused by distal catheter malposition or excessive intraperitoneal length^(15, 16). Such pain may resolve after catheter shortening or repositioning^(15, 16). A less anticipated complication was persistent, otherwise unexplained abdominal pain that improved only after replacement of one commercial catheter brand with another. Previous retrospective observations from our single-centre unit identified that Ares®

peritoneal catheters were associated with a higher frequency of abdominal pain requiring revision than Bactiseal®, while greater functional activity was also associated with symptoms⁽¹⁷⁾. These observations raised the possibility that commercially available catheters with similar intended functions may differ in biochemical, mechanical or surface properties that influence their behaviour in vivo.

To investigate this possibility, we conducted a prospective comparative laboratory study examining antibiotic content, degradation profiles, elution, antimicrobial activity, catheter dimensions, mechanical properties and surface characteristics of commercially available antibiotic-impregnated shunt catheters. A retrospective single centre quality improvement dataset was additionally analysed to provide clinical context for the observed laboratory differences.

Methods

Manufacturers were contacted directly and invited to provide antibiotic-impregnated shunt catheters for comparative testing. Integra LifeSciences supplied Bactiseal®, Medtronic supplied Ares®, and Christoph Miethke GmbH & Co. KG supplied XABO®. Delta Surgical was approached to provide DESU® catheters but declined participation. Three supplied units of each available product were used across the experimental analyses. For Ares®, the supplied material comprised one peritoneal catheter (REF 93092) and two catheter kits (REF 95001), all from lot 0010770596. Product identifiers and lot numbers for Bactiseal® and XABO® are reported in Table 1.

All catheters were within their stated shelf life and were transported and stored according to the manufacturers' specified environmental and temperature requirements. The prescribed storage conditions were maintained throughout, with no breach or compromise to sample integrity.

Manufacturer	Product	Components supplied	Reference number(s)	Lot number	Radiopaque composition	Manufacturer-specified storage
Integra LifeSciences	Bactiseal®	Ventricular and peritoneal catheters	82-3072	6350366	Barium sulphate-containing radiopaque silicone	Store between 2°C and 27°C
Medtronic	Ares®	Ventricular and peritoneal catheters	93092 and 95001	0010770596	Barium sulphate-containing radiopaque silicone	Store between 2°C and 27°C
Christoph Miethke GmbH & Co. KG	XABO®	Ventricular and peritoneal catheters	ST08300120	30218340	Barium sulphate-containing radiopaque silicone	Shelf storage; stable at temperatures up to 30°C

Table 1. Manufacturer and traceability details of the antibiotic-impregnated catheter samples. Product identifiers, lot numbers, material composition, and storage conditions were recorded from the original packaging and manufacturer documentation.

Competing interests: The authors declare no competing interests. The provision of catheter samples by the manufacturers is disclosed as in-kind support. The manufacturers had no role in the study design, data collection, analysis, interpretation, manuscript preparation, or decision to submit the work for publication.

Antibiotic Content

Antibiotic content was defined as the quantity of clindamycin and rifampicin incorporated within the catheter matrix. The nominal manufacturer-specified concentrations were 0.15% for clindamycin and 0.054% for rifampicin. Measured concentrations were reported as mass

percentage (m%; grams of analyte per 100 g of catheter) and additionally expressed as a percentage of the nominal specified concentration to facilitate comparison between products.

Equal lengths of ventricular and peritoneal catheter from each product were subjected to exhaustive chemical extraction at Labor LS SE & Co. KG. Extraction was performed by solvent-induced matrix swelling using three sequential organic solvents under continuous agitation. The pooled extracts were analysed by ultra-performance liquid chromatography–mass spectrometry (UPLC–MS) to quantify clindamycin, rifampicin and detectable rifampicin-related compounds.

Rifampicin purity, active-ingredient assay, and organic impurities

Rifampicin integrity was assessed by comparing the proportion of intact rifampicin within the total chromatographic peak area against the European Pharmacopoeia rifampicin reference standard, which demonstrated an intact-rifampicin peak-area fraction of 96.96%. The analysis also quantified the relative abundance of principal rifampicin-related compounds and degradation products within each catheter extract. A deviation of $\geq 5\%$ from the manufacturer-declared assay value was considered potentially meaningful, based on pharmaceutical stability guidance.

Equal lengths of catheter were sectioned and weighed before single-point exhaustive extraction in methanol. Solvent-induced matrix swelling was performed under continuous agitation for 24 h to recover compounds embedded within the silicone matrix. Extracts were analysed by high-performance liquid chromatography coupled with mass spectrometry (HPLC–MS) to determine the relative chromatographic abundance of intact rifampicin and associated degradation products.

Antibiotic elution over time

Equal-length segments of the peritoneal components of Ares®, Bactiseal®, and XABO® antibiotic-impregnated catheters were connected to sterile drainage systems and continuously perfused with normal saline at 20 mL/h using an Evo IQ infusion system (Baxter Healthcare). Perfusate temperature was maintained at 37°C using a Biegler 685 intravenous fluid warmer to approximate physiological conditions. The system operated in a single-pass configuration without recirculation.

The three catheter products were tested concurrently in triplicate using peritoneal catheter segments only. Perfusate was collected aseptically at 1, 3, 5, and 8 weeks and analysed at the Bristol Antimicrobial Reference Laboratory. Clindamycin and rifampicin concentrations were quantified using high-performance liquid chromatography and liquid chromatography–mass spectrometry to characterise antibiotic elution over time.

Antimicrobial activity

Longitudinal antimicrobial activity was assessed using a modified agar diffusion assay over 60 days. *Staphylococcus epidermidis* was cultured on CASO agar for 18–24 h, after which a bacterial suspension was prepared in 0.9% sodium chloride and adjusted to $1\text{--}5 \times 10^8$ colony-forming units (CFU)/mL. Equal-length catheter segments from Ares®, Bactiseal®, and XABO® were tested in triplicate and aseptically placed on inoculated CASO agar plates. A 5 µg ciprofloxacin disc was positioned centrally on each plate as a positive control. Catheter-associated zones of inhibition were measured in millimetres throughout the 60-day study period to assess the magnitude and persistence of antimicrobial activity.

Antimicrobial activity was classified according to predefined laboratory criteria. A measurable inhibition zone extending beyond the external diameter of the catheter was considered evidence of continued antimicrobial activity, and therefore a good antimicrobial effect, whereas absence of a clearly demarcated inhibition zone was considered insufficient antimicrobial activity.

Catheter dimensions

The ventricular and peritoneal components of each catheter type were assessed by the UCL Medical Physics and Biomedical Engineering team using three-dimensional computed tomography. Internal diameter, external diameter and wall thickness were measured along the catheter length and compared with the corresponding manufacturer-stated nominal dimensions^(18, 19, 20). No dimensional manufacturing tolerances were provided by the manufacturers or identified in the publicly available manufacturer or regulatory documentation reviewed, therefore, measured differences were interpreted descriptively and not as evidence that a catheter was outside manufacturing specification. Measured values were additionally expressed as percentage differences from the stated dimensions to facilitate comparison between products.

Product	Catheter component	Body material	Internal diameter (µm)	External diameter (µm)	Length	Length markers	Tip configuration
Ares®	Ventricular	Barium sulphate-filled silicone elastomer	1,270	2,540	23 cm	Numerical length markers	Bullet-shaped tip with 32 inlet holes arranged in four rows of eight
Ares®	Peritoneal	Barium sulphate-filled silicone elastomer	1,270	2,540	120 cm	None	Open-ended; no slits
Bactiseal®	Ventricular	Barium sulphate-filled silicone elastomer	1,400 or 1,270	2,690 or 2,540	14, 15, or 23 cm	One dot at 10 cm and two dots at 15 cm	Bullet-shaped tip with 24 inlet holes arranged in three rows of eight
Bactiseal®	Peritoneal	Barium sulphate-filled silicone elastomer	990 or 1,270	2,200 or 2,540	120 cm	None	Open-ended; no slits
XABO®	Ventricular	Barium sulphate-filled silicone elastomer	1,200	2,500	18 cm	Markers at 1-cm intervals	Sixteen flow holes; supplied with a preloaded stainless-steel stylet and optional deflector
XABO®	Peritoneal	Barium sulphate-filled silicone elastomer	1,200	2,500	60 or 120 cm	Not stated	Open-ended and trimmable

Table 2. Manufacturer-declared material composition and design specifications of the evaluated antibiotic-impregnated shunt catheters^(18, 19, 20). No dimensional manufacturing tolerances were supplied by the manufacturers or identified in the publicly available product documentation reviewed; nominal dimensions are therefore presented for descriptive comparison only.

Rigidity and elasticity

Equal-length, weight-matched segments of the peritoneal components of Ares®, Bactiseal®, and XABO® were assessed by nanoindentation following saline perfusion. Elastic modulus was measured as an indicator of material stiffness, rigidity and elasticity, with higher values representing greater resistance to elastic deformation.

Surface microstructure

Ventricular and peritoneal catheter segments from Ares®, Bactiseal®, and XABO® were perfused with normal saline at 20 mL/h and maintained at 37°C for 8 weeks. Following completion of the perfusion period, the used catheter segments were examined using GeminiSEM scanning electron microscopy to assess surface microstructure and adherent deposits.

Retrospective clinical quality-improvement analysis

A retrospective single-centre quality-improvement project, approved and registered by the Trust's Quality and Safety team, was undertaken to investigate the relationship between shunt catheter type and otherwise unexplained abdominal pain following shunt surgery. The sampling strategy aimed to identify at least 100 consecutive patients implanted with Ares® catheters and at least 100 consecutive patients implanted with Bactiseal® catheters. Cases were selected sufficiently far back in the clinical record to allow a minimum of 12 months of postoperative clinical follow-up, enabling assessment of subsequent abdominal pain, investigation of its cause, and any treatment or shunt revision undertaken.

Demographic and clinical variables included age, sex, primary diagnosis leading to shunt insertion, functional status assessed using the modified Rankin Scale (mRS), level of physical activity, catheter type, presence of abdominal pain, subsequent management and requirement for shunt revision. Comorbidities were also reviewed where available. Clinical records were examined to determine whether abdominal pain had an identifiable alternative cause or remained otherwise unexplained.

The primary clinical outcome was the occurrence of otherwise unexplained abdominal pain according to catheter type. Subsequent shunt revision was examined as a secondary outcome. Demographic, diagnostic and functional variables were evaluated as potential factors associated with abdominal pain.

Statistical analysis

Laboratory data were analysed primarily descriptively because the number of independent catheter samples was limited. Measurements obtained repeatedly from the same catheter or specimen were not treated as independent observations. Antibiotic content, rifampicin chromatographic profiles, elution data, catheter dimensions, elastic modulus and scanning electron microscopy findings were therefore reported as measured values or descriptive summaries rather than subjected to confirmatory between-product hypothesis testing. Where triplicate measurements were available, including inhibition-zone testing, results are presented as mean ± standard deviation. Numerical differences between products were interpreted as descriptive trends and not as evidence of statistical superiority.

For the retrospective clinical analysis, the association between catheter type and abdominal pain was first assessed across Ares®, Bactiseal®, plain and silver-labelled catheters using the χ^2 test. Pairwise comparisons were performed using two-sided Fisher's exact tests, with adjustment for multiple comparisons. Effect sizes were expressed as odds ratios (OR) with 95% confidence intervals (CI).

Multivariable logistic regression was then used to assess the independent association between catheter type and abdominal pain after adjustment for age, sex, primary diagnosis, modified Rankin Scale score and activity level. Bactiseal® was used as the reference catheter category. Adjusted odds ratios with 95% confidence intervals are reported. Subsequent shunt revision was analysed separately as a secondary clinical outcome. All tests were two-sided, with statistical significance defined as $p < 0.05$.

Statistical analyses were performed using Python version 3.13.5 (Python Software Foundation), with SciPy version 1.17.0 for inferential tests and statsmodels version 0.14.6 for multivariable logistic regression.

Results

Antibiotic Content

Measured clindamycin concentrations varied among catheter types and components. The XABO® ventricular catheter most closely approximated the declared concentration of 0.1500 m%, containing 0.1471 m% (98.1% of the specified value). This was followed by the Ares® peritoneal and ventricular catheters, which contained 0.1408 m% (93.9%) and 0.1400 m% (93.3%), respectively. The XABO® peritoneal catheter contained 0.1368 m% (91.2%), while Bactiseal® contained 0.1291 m% (86.1%) in the peritoneal component and 0.1094 m% (72.9%) in the ventricular component.

For rifampicin, the XABO® peritoneal catheter most closely matched the declared concentration of 0.0540 m%, containing 0.0510 m% (94.4% of the specified value), while the XABO® ventricular catheter contained 0.0592 m% (109.6%). Bactiseal® peritoneal contained 0.0401 m% (74.3%), followed by Ares® peritoneal at 0.0381 m% (70.6%), Ares® ventricular at 0.0368 m% (68.1%), and Bactiseal® ventricular at 0.0299 m% (55.4%).

Rifampicin-related compounds

Three rifampicin-related compounds not included in the manufacturer-declared antibiotic specifications were identified: rifampicin quinone, 25-desacetyl-rifampicin and 3-formyl-rifampicin SV.

Rifampicin quinone concentrations were low across all catheter types, ranging from 0.0007 to 0.0012 m%. The lowest concentration was measured in the Bactiseal® peritoneal catheter (0.0007 m%), while the highest was observed in the Ares® ventricular catheter (0.0012 m%). Bactiseal® ventricular, Ares® peritoneal and XABO® peritoneal catheters each contained 0.0008 m%, while XABO® ventricular contained 0.0010 m%.

XABO® contained the lowest concentrations of 25-desacetyl-rifampicin, measuring 0.0021 m% in the ventricular and 0.0025 m% in the peritoneal component. Corresponding concentrations were 0.0080 m% and 0.0100 m% for Bactiseal® ventricular and peritoneal catheters, and 0.0114 m% and 0.0108 m% for Ares®, respectively.

For 3-formyl-rifampicin SV, the compound was below the analytical detection limit in both XABO® components. Measurable concentrations were identified in Ares® and Bactiseal®, with Ares® showing the highest values.

Product/component	Clindamycin (m%)	Clindamycin (% nominal)	Rifampicin (m%)	Rifampicin (% nominal)	Rifampicin quinone (m%)	25-desacetyl-rifampicin (m%)	3-formyl-rifampicin SV (m%)
Ares® peritoneal	0.1408	93.9	0.0381	70.6	0.0008	0.0108	0.0211
Ares® ventricular	0.1400	93.3	0.0368	68.1	0.0012	0.0114	0.0189
Bactiseal® peritoneal	0.1291	86.1	0.0401	74.3	0.0007	0.0100	0.0156
Bactiseal® ventricular	0.1094	72.9	0.0299	55.4	0.0008	0.0080	0.0147
XABO® peritoneal	0.1368	91.2	0.0510	94.4	0.0008	0.0025	<LOD
XABO® ventricular	0.1471	98.1	0.0592	109.6	0.0010	0.0021	<LOD
Nominal specification	0.1500	100	0.0540	100	—	—	—

Table 3. Measured antibiotic content and rifampicin-related compounds in commercially available antibiotic-impregnated shunt catheters. Clindamycin and rifampicin are reported as mass percentage (m%; grams of analyte per 100 g of catheter) and as percentage of the manufacturer-specified nominal concentration. Rifampicin-related compounds are reported as measured mass percentages because no nominal manufacturer specifications were available. LOD, limit of detection. “< LOD” indicates that the analyte concentration was below the analytical detection limit.

Rifampicin purity, active-ingredient assay, and organic impurities

Rifampicin purity, expressed as the proportion of total peak area attributable to intact rifampicin, differed among catheter types and components. Against the European Pharmacopoeia reference-standard value of 96.96%, XABO® demonstrated the highest intact rifampicin proportions, measuring 89.77% in the peritoneal component (92.6% of the reference-standard value) and 85.24% in the ventricular component (87.9% of the reference-standard value). Bactiseal® showed intermediate values of 59.12% (61.0% of the reference-standard value) and 54.23% (55.9% of the reference-standard value) in the peritoneal and ventricular components, respectively, while Ares® demonstrated 50.86% (52.5% of the reference-standard value) and 49.08% (50.6% of the reference-standard value), respectively.

The relative abundance of rifampicin degradation products also varied between products. Rifampicin quinone accounted for 1.19–2.67% of total chromatographic peak area across catheter samples, compared with 0.83% in the European Pharmacopoeia reference standard. XABO® contained 1.19% in the peritoneal and 1.36% in the ventricular component, Bactiseal® 1.32% and 1.98%, and Ares® 1.53% and 2.67%, respectively.

For 25-desacetyl-rifampicin, XABO® demonstrated the lowest proportions, measuring 1.95% in the peritoneal and 1.27% in the ventricular component. Corresponding values were 17.01% and 19.07% for Bactiseal® and 20.20% and 22.06% for Ares®. The European Pharmacopoeia reference standard contained 0.43%.

3-Formyl-rifampicin SV was below the analytical detection limit in both XABO® components and in the Bactiseal® peritoneal component. It accounted for 22.52% of total peak area in the Bactiseal® ventricular catheter and 25.44% and 23.40% in the Ares® peritoneal and ventricular components, respectively; the compound was below the detection limit in the reference standard.

Overall, XABO® retained the greatest proportion of intact rifampicin and showed the lowest relative abundance of the principal degradation products, most closely approaching the chromatographic profile of the European Pharmacopoeia reference standard.

Product/component	Intact rifampicin (% peak area)	% of EP reference value	Rifampicin quinone (%)	25-desacetyl-rifampicin (%)	3-formyl-rifampicin SV (%)
Ares® peritoneal	50.86	52.5	1.53	20.20	25.44
Ares® ventricular	49.08	50.6	2.67	22.06	23.40
Bactiseal® peritoneal	59.12	61.0	1.32	17.01	<LOD
Bactiseal® ventricular	54.23	55.9	1.98	19.07	22.52
XABO® peritoneal	89.77	92.6	1.19	1.95	<LOD
XABO® ventricular	85.24	87.9	1.36	1.27	<LOD
EP reference standard	96.96	100	0.83	0.43	<LOD

Table 4. Rifampicin chromatographic profile and relative abundance of degradation products in antibiotic-impregnated shunt catheters. Values represent percentage of total chromatographic peak area. Intact rifampicin is additionally expressed as a percentage of the European Pharmacopoeia reference-standard value (96.96%). EP, European Pharmacopoeia. LOD, limit of detection. “< LOD” indicates that the analyte was below the analytical detection limit.

Antibiotic elution over time

Elution testing was performed using peritoneal catheter segments only.

Elution profiles differed between the peritoneal catheter types. For rifampicin, XABO® demonstrated the highest measured concentration at week 1 (0.0146 mg/L), followed by Ares® (0.00392 mg/L) and Bactiseal® (0.00259 mg/L). The same pattern was observed at week 3, with concentrations of 0.0201, 0.00411 and 0.00263 mg/L, respectively. Rifampicin was below the analytical limit of quantification in all three catheter groups at weeks 5 and 8.

Clindamycin remained detectable throughout the 8-week study. At week 3, concentrations were highest for Ares® (0.665 mg/L), followed by Bactiseal® (0.571 mg/L) and XABO® (0.195 mg/L). Ares® demonstrated the highest clindamycin concentrations at every sampled time point, while Bactiseal® exceeded XABO® from week 3 onwards. The non-monotonic concentration profile, including the week-3 peak, is reported as measured by the analytical laboratory.

Overall, XABO® demonstrated the greatest early rifampicin elution, whereas Ares® showed the highest and most sustained clindamycin concentrations.

Antibiotic	Catheter	Week 1 (mg/L)	Week 3 (mg/L)	Week 5 (mg/L)	Week 8 (mg/L)
Rifampicin	Bactiseal®	0.00259	0.00263	< LOQ	< LOQ
	Ares®	0.00392	0.00411	< LOQ	< LOQ
	XABO®	0.0146	0.0201	< LOQ	< LOQ
Clindamycin	Bactiseal®	0.0190	0.571	0.0390	0.0544
	Ares®	0.182	0.665	0.0706	0.106
	XABO®	0.0478	0.195	0.0265	0.0324

Table 5. Clindamycin and rifampicin concentrations measured in perfusate from the peritoneal components of Ares®, Bactiseal®, and XABO® catheters over 8 weeks. For rifampicin, values below the laboratory reporting threshold of 0.002 mg/L are reported as <LOQ. LOQ, limit of quantification.

Antimicrobial activity

All three catheter types maintained measurable antimicrobial activity against *Staphylococcus epidermidis* throughout the 60-day study. Inhibition-zone diameter decreased progressively over time for each product, consistent with a gradual reduction in antimicrobial effect while remaining detectable at day 60.

XABO® demonstrated the largest mean inhibition zone at every sampled time point, followed by Ares® and Bactiseal®. Mean inhibition-zone diameter decreased from 15.67 ± 0.29 mm at baseline to 6.00 ± 0.00 mm at day 60 for XABO®, from 14.43 ± 0.12 mm to 5.00 ± 0.00 mm for

Ares®, and from 14.00 ± 0.00 mm to 4.50 ± 0.00 mm for Bactiseal®. The same numerical ranking was maintained throughout the observation period.

Because only three replicate measurements were available per catheter type, these between-product differences were interpreted descriptively rather than as confirmatory evidence of statistical superiority.

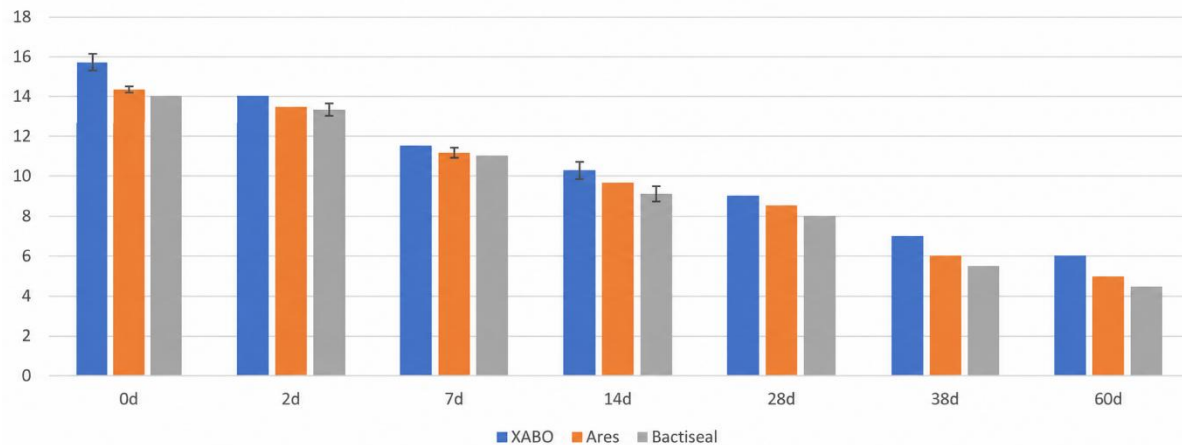


Figure 1. Longitudinal antimicrobial activity of XABO®, Ares®, and Bactiseal® against *Staphylococcus epidermidis* over 60 days. Bars represent mean inhibition-zone diameter from three replicate measurements; error bars represent standard deviation (SD). Where no error bar is visible, the SD was 0.00 because all three replicate measurements were identical. All three catheter types retained measurable antimicrobial activity at day 60.

Catheter dimensions

Three-dimensional computed tomography demonstrated modest differences between measured and manufacturer-stated nominal catheter dimensions. Among the peritoneal catheters, Ares® had an external diameter of 2,645 µm compared with a nominal 2,540 µm (+4.1%) and an internal diameter of 1,218 µm compared with 1,270 µm (−4.1%). XABO® measured 2,566 µm externally compared with a nominal 2,500 µm (+2.6%) and 1,185 µm internally compared with 1,200 µm (−1.2%). Bactiseal® measured 2,241 µm externally compared with a nominal 2,200 µm (+1.9%) and 948 µm internally compared with 1,000 µm (−5.2%).

For the ventricular catheters, Bactiseal® measured 2,710 µm externally compared with a nominal 2,700 µm (+0.4%) and 1,439 µm internally compared with 1,400 µm (+2.8%). Ares® measured 2,611 µm externally compared with 2,540 µm (+2.8%) and 1,259 µm internally compared with 1,270 µm (−0.9%). XABO® measured 2,584 µm externally compared with 2,500 µm (+3.4%) and 1,196 µm internally compared with 1,200 µm (−0.3%).

Measured wall thickness remained broadly similar across products, ranging from 661 to 701 µm. As no dimensional manufacturing tolerances were supplied by the manufacturers or identified in the publicly available product documentation reviewed, these deviations from nominal dimensions were interpreted descriptively and not as evidence that any catheter was outside specification.

Catheter	Component	Measured OD (μm)	Nominal OD (μm)	OD deviation (%)	Measured ID (μm)	Nominal ID (μm)	ID deviation (%)	Wall thickness (μm)
Bactiseal®	Peritoneal	2,241	2,200	+1.9	948	1,000	-5.2	661
Ares®	Peritoneal	2,645	2,540	+4.1	1,218	1,270	-4.1	695
XABO®	Peritoneal	2,566	2,500	+2.6	1,185	1,200	-1.3	696
Bactiseal®	Ventricular	2,710	2,700	+0.4	1,439	1,400	+2.8	698
Ares®	Ventricular	2,611	2,540	+2.8	1,259	1,270	-0.9	701
XABO®	Ventricular	2,584	2,500	+3.4	1,196	1,200	-0.3	696

Table 6. Comparison of measured and manufacturer-stated nominal dimensions of the ventricular and peritoneal components of Bactiseal®, Ares®, and XABO® catheters. Percentage deviation was calculated relative to the manufacturer-stated nominal dimension. Positive values indicate a measured dimension greater than nominal, and negative values indicate a smaller measured dimension. No dimensional manufacturing tolerances were supplied by the manufacturers or identified in the product documentation reviewed; deviations are therefore presented descriptively and should not be interpreted as specification failures. OD, external diameter; ID, internal diameter.

Rigidity and elasticity

After completion of the saline-perfusion experiments, the peritoneal catheter segments were assessed for rigidity and elasticity. Elastic modulus differed numerically among the three catheter types. XABO® demonstrated replicate measurements of 435,452.6 Pa and 440,368.9 Pa, corresponding to a mean elastic modulus of 437,910.8 Pa (0.438 MPa). Bactiseal® measured 268,219.2 Pa and 267,430.0 Pa, with a mean of 267,824.6 Pa (0.268 MPa), while Ares® measured 235,487.0 Pa and 192,272.7 Pa, with a mean of 213,879.9 Pa (0.214 MPa).

Thus, XABO® showed the highest measured elastic modulus, exhibiting the greatest resistance to elastic deformation, followed by Bactiseal® and Ares®. As only two measurements were available for each catheter type, these differences were interpreted descriptively and not as confirmatory evidence of statistical superiority.

Catheter	Measurement 1 (Pa)	Measurement 2 (Pa)	Mean elastic modulus (Pa)	Mean elastic modulus (MPa)
Ares®	235,487.0	192,272.7	213,879.9	0.214
Bactiseal®	268,219.2	267,430.0	267,824.6	0.268
XABO®	435,452.6	440,368.9	437,910.8	0.438

Table 7. Elastic modulus of Ares®, Bactiseal®, and XABO® peritoneal catheter segments following completion of the saline-perfusion experiments. Two measurements were obtained for each catheter type. Higher elastic modulus indicates greater material stiffness and lower elastic deformability. Given the limited number of measurements, results are presented descriptively and were not used to establish statistical superiority.

Surface microstructure

Following 8 weeks of aseptic saline perfusion at 20 mL/h and 37°C, ventricular and peritoneal catheter segments were examined by scanning electron microscopy. Surface morphology and adherent deposits differed qualitatively among the three products. Ares® showed an uneven surface with scattered particulate material and focal larger aggregates. Bactiseal® appeared to demonstrate the greatest density of adherent deposits, with numerous discrete particles and clustered accumulations across the examined surface. XABO® retained a comparatively more

uniform underlying surface, although small deposits and occasional larger aggregates were also present.

Given the prolonged exposure to normal saline, the observed deposits were considered most likely to represent precipitated salt residues. However, no elemental or compositional analysis was performed; therefore, their identity remains presumptive.

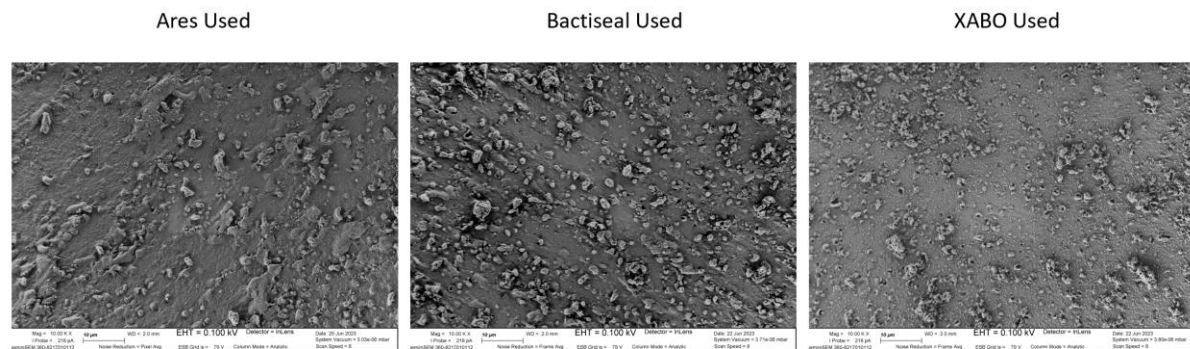


Figure 2. Scanning electron micrographs of used Ares®, Bactiseal®, and XABO® catheters demonstrating differences in surface morphology and adherent deposits. Images were acquired at $\times 10,000$ magnification; scale bar, 10 μm .

Retrospective clinical analysis

The retrospective clinical analysis included 395 patients: 182 with Ares®, 108 with Bactiseal®, 82 with plain catheters and 23 with silver-labelled catheters.

Among antibiotic-impregnated systems, the clinical analysis included only catheter types in routine use at the single-centre neurosurgical unit during the QIP period. Ares® and Bactiseal® were the antibiotic-impregnated catheters used locally at that time. XABO® and DESU® were not in routine clinical use and therefore were not represented in the comparative clinical cohort. Plain and silver-labelled catheters were retained as additional contemporaneous comparator groups.

Mean age, sex, and primary diagnosis were similar across patient groups. Patients presenting with unexplained abdominal pain had a lower median modified Rankin Scale score and were more frequently classified as active than patients without unexplained abdominal pain.

Otherwise unexplained abdominal pain was recorded in 90/182 Ares® patients (49.5%), compared with 12/108 Bactiseal® patients (11.1%), 10/82 patients with plain catheters (12.2%) and 3/23 patients with silver-labelled catheters (13.0%; overall $\chi^2(3)=67.68$, $p<0.001$). On pairwise analysis, Ares® was associated with greater odds of abdominal pain than Bactiseal® (OR 7.83, 95% CI 4.02–15.24; $p<0.001$), plain catheters (OR 7.04, 95% CI 3.42–14.51; $p<0.001$) and silver-labelled catheters (OR 6.52, 95% CI 1.87–22.71; $p<0.001$). No significant differences were identified between Bactiseal®, plain and silver-labelled catheters.

After adjustment for age, sex, primary diagnosis, modified Rankin Scale score and activity level, catheter type remained independently associated with otherwise unexplained abdominal pain (overall $p<0.001$). Using Bactiseal® as the reference category, Ares® remained associated with substantially greater odds of abdominal pain (adjusted OR 6.89, 95% CI 2.58–18.43; $p<0.001$), whereas plain catheters (adjusted OR 1.35, 95% CI 0.38–4.79; $p=0.638$) and silver-labelled catheters (adjusted OR 1.68, 95% CI 0.31–9.09; $p=0.550$) were not significantly different from Bactiseal®.

Subsequent shunt revision due to no other cause was recorded in 20/182 Ares® patients (11.0%), 3/108 Bactiseal® patients (2.8%), 4/82 patients with plain catheters (4.9%) and 1/23 patients with silver-labelled catheters (4.3%; overall $p=0.044$). Among patients who developed abdominal pain, subsequent shunt revision was performed in 20/90 Ares® patients (22.2%), 3/12 Bactiseal® patients (25.0%), 4/10 patients with plain catheters (40.0%) and 1/3 patients with silver-labelled catheters (33.3%). The proportion requiring revision did not differ significantly between catheter groups ($\chi^2(3)=1.69$, $p=0.640$).

Characteristic	Ares® (n=182)	Bactiseal® (n=108)	Plain (n=82)	Silver-labelled (n=23)	p
Age, years, mean $\pm$ SD	53.9 $\pm$ 14.9	56.5 $\pm$ 16.0	52.3 $\pm$ 16.0	53.0 $\pm$ 16.3	0.291
Male, n (%)	102 (56.0)	64 (59.3)	47 (57.3)	14 (60.9)	0.940
NPH, n (%)	130 (71.4)	77 (71.3)	52 (63.4)	15 (65.2)	
Post-haemorrhagic, n (%)	32 (17.6)	20 (18.5)	21 (25.6)	6 (26.1)	
IIH, n (%)	13 (7.1)	3 (2.8)	5 (6.1)	0	
CSF leak, n (%)	3 (1.6)	5 (4.6)	3 (3.7)	2 (8.7)	
Tumour, n (%)	4 (2.2)	3 (2.8)	1 (1.2)	0	0.446†
mRS, median [IQR]	1 [0–3]	1 [0–3]	1 [0–3]	1 [0–3]	<0.001
Active, n (%)	97 (53.3)	54 (50)	35 (42.6)	10 (43.47)	<0.001
Abdominal pain, n (%)	90 (49.5)	12 (11.1)	10 (12.2)	3 (13.0)	<0.001
Subsequent revision, n (%)	20 (11.0)	3 (2.8)	4 (4.9)	1 (4.3)	0.044

Table 8. Demographic and clinical characteristics of the retrospective quality-improvement cohort according to shunt catheter type. Values are presented as mean $\pm$ standard deviation (SD), median [interquartile range (IQR)] or n (%), as appropriate. †p refers to the overall distribution of primary diagnoses across catheter groups. ‡Revision analysis was restricted to patients who developed abdominal pain; because of small cell counts, an exact test was used. NPH, normal-pressure hydrocephalus; IIH, idiopathic intracranial hypertension; CSF, cerebrospinal fluid; mRS, modified Rankin Scale.

Discussion

Hydrocephalus is a major global neurosurgical condition, with an annual incidence of approximately 30–300 cases per 100,000 population and nearly 400,000 new paediatric cases each year^(21, 22). This burden makes ventriculoperitoneal shunt insertion one of the most common neurosurgical procedures worldwide⁽²⁾.

The economic consequences are substantial. In the United States, shunt-related admissions cost more than US\$2 billion annually^(23, 24), and approximately 75% of hydrocephalus-related hospital expenditure is attributable to complications or failure after previous treatment^(25, 26). The burden is even greater in low- and middle-income countries⁽²⁷⁾, where paediatric hydrocephalus may be more than 20 times as common^(21, 28), post-infectious disease accounts for up to 60% of cases^(24, 29, 30, 31), and access to care is limited by hardware costs, restricted hospital resources and severe workforce shortages⁽³²⁾. In parts of sub-Saharan Africa, one neurosurgeon may serve 5–10

million people⁽²⁴⁾, while the economic losses associated with paediatric hydrocephalus in low-resource settings have been estimated to exceed US\$50 billion annually⁽³⁰⁾.

Antibiotic-impregnated shunts may reduce this burden^(33, 34, 35). The BASICS economic analysis found them likely to be cost-effective despite costing approximately twice as much as standard catheters, because shunt infection is expensive to manage⁽²⁾. Evidence from low-resource settings is less consistent and is influenced by operative sterility, perioperative care, postoperative surveillance and local infection patterns^(10, 36). Nevertheless, preventing even a small number of infections or revisions may justify the additional acquisition cost⁽³⁷⁾.

Shunt dependence also imposes considerable physical and psychological consequences, including pain, anxiety about malfunction, restrictions on activity and uncertainty as to whether symptoms indicate shunt failure^(38, 39), all of which may intensify with each additional surgical intervention. These effects may impair education, employment, independence and quality of life⁽³⁸⁾. Successful treatment at the index procedure is therefore critical^(26, 40). UK registry data showed that 49.0% of shunt procedures were revisions⁽⁴¹⁾, while international data reported a similar revision rate of 51.2%^(24, 40), making device selection an important component of failure prevention.

Against this background, the present study identified product-specific biochemical and physical differences among commercially available antibiotic-impregnated shunt catheters. To our knowledge, this is the first prospective comparison to examine these characteristics across multiple analytical domains. Because the number of independent catheter samples was limited, most laboratory comparisons were descriptive and should not be interpreted as demonstrating statistical non-equivalence or superiority. Nevertheless, XABO® most closely matched the declared antibiotic concentrations, retained the greatest proportion of intact rifampicin and contained the lowest relative abundance of major rifampicin degradation products. Ares® showed comparatively consistent antibiotic content between ventricular and peritoneal components but lower rifampicin purity, while Bactiseal® showed greater component-level variation, with its ventricular catheter containing the lowest measured clindamycin and rifampicin concentrations.

Importantly, the accompanying retrospective clinical analysis demonstrated a statistically significant association between catheter type and otherwise unexplained abdominal pain. This association persisted after adjustment for age, sex, primary diagnosis, modified Rankin Scale score and activity level, with Ares® remaining associated with substantially greater odds of abdominal pain than Bactiseal®. These clinical findings do not establish that any individual biochemical or mechanical property identified in the laboratory caused the symptoms, but they indicate that nominally similar catheter systems may behave differently in vivo. Accordingly, the combined laboratory and clinical observations should be regarded as hypothesis-generating rather than evidence of causality or clinical superiority.

The laboratory findings do not indicate contamination or regulatory non-compliance, as the study was not designed as a formal release assay and included a limited number of samples. They do, however, demonstrate that nominally similar products may reach the point of implantation with different biochemical profiles. Rifampicin is less chemically stable than clindamycin, and differences in sterilisation, packaging and storage may therefore influence residual active drug and degradation-product formation. XABO® undergoes electron-beam sterilisation and is supplied in gas-tight, argon-filled packaging designed to minimise exposure to oxygen and moisture. It may be stored at temperatures up to 30°C and has a manufacturer-stated shelf life of up to 5 years. In contrast, Ares® and Bactiseal® undergo steam sterilisation. Ares® is specified for

storage below 27°C with a shelf life of up to 3 years, while Bactiseal® requires storage between 2°C and 27°C with a manufacturer declared shelf life of up to 1 year, with both protected from direct light. These differences may contribute to the observed variation in rifampicin content, intact rifampicin and degradation-product profiles, although the present study was not designed to determine the independent effects of sterilisation, packaging or storage conditions. The ICH Q1A(R2) stability guidance defines a 5% change in assay from the initial value as a significant change during stability testing. In the present cross-sectional catheter measurements, several observed deviations from the nominal antibiotic content exceeded this magnitude, reinforcing the need for formal product-specific stability studies across shelf life.

The products also showed distinct elution patterns. XABO® produced the highest rifampicin concentrations during the first 3 weeks, after which rifampicin was below the limit of quantification in all groups. Clindamycin remained detectable throughout the 8-week study, with Ares® producing the highest concentrations at each interval. These differences may be relevant to previously reported otherwise unexplained abdominal pain associated with some peritoneal catheters⁽¹⁷⁾, although the mechanism remains uncertain. Potential contributors include local tissue exposure to eluted antibiotics, differences in catheter stiffness and deformability, external dimensions, and surface characteristics, any of which could influence interaction with the peritoneum or omentum. The present study was not designed to determine which, if any, of these factors is causally responsible for symptoms.

All three catheters retained measurable antimicrobial activity against *Staphylococcus epidermidis* throughout the 60-day study. XABO® produced the largest mean inhibition zones at each sampled time point, followed by Ares® and Bactiseal®. Given the limited number of replicate measurements, these between-product differences should be interpreted descriptively rather than as confirmatory evidence of statistical superiority. Importantly, antimicrobial activity did not directly parallel clindamycin elution: Ares® demonstrated the highest clindamycin concentrations, whereas XABO® produced the largest inhibition zones. This suggests that antimicrobial performance may reflect the combined effects of antibiotic concentration and integrity, local surface availability, catheter matrix characteristics and diffusion through the surrounding medium rather than any single elution parameter.

The physical analyses also identified product-specific differences. 3D CT demonstrated variation in internal and external catheter dimensions, although wall thickness remained broadly similar. Measured dimensions were generally close to the corresponding manufacturer-stated nominal values, however, no dimensional manufacturing tolerances were provided by the manufacturers or identified in the product documentation reviewed, and these differences should therefore be interpreted descriptively rather than as specification failures. Nanoindentation of the peritoneal components showed the highest measured elastic modulus in XABO®, followed by Bactiseal® and Ares®, indicating differences in stiffness and deformability. Following 8 weeks of saline perfusion, scanning electron microscopy demonstrated qualitative differences in surface morphology and adherent deposits, with Bactiseal® appearing to show the greatest density of deposits, Ares® showing more scattered particulate material and XABO® retaining a comparatively more uniform underlying surface. These mechanical and surface differences provide additional plausible mechanisms by which catheter products could interact differently with surrounding tissues in vivo.

These findings may have relevance beyond a single institution, as antibiotic-impregnated shunt systems are used across multiple healthcare settings and similar patterns of primary shunt insertion and revision have been reported in national registry data from the United Kingdom, Ireland, Australia and Aotearoa New Zealand⁽²²⁾. Comparative product data may therefore

support more informed device selection and procurement, particularly when clinicians must substitute an unfamiliar catheter because of changes in local availability or supply. Rather than assuming interchangeability, catheter choice may need to consider product-specific biochemical, mechanical and dimensional characteristics alongside individual patient requirements.

Limitations and Future Work

Several limitations should be acknowledged. The laboratory component used a limited number of catheter samples and manufacturing lots, restricting assessment of inter-batch variability and the generalisability of the measured differences. Several laboratory comparisons were therefore descriptive rather than confirmatory, and the in-vitro environment cannot fully reproduce cerebrospinal fluid composition, tissue interaction, protein binding, catheter movement or host biological responses. Elution was assessed at predefined intervals rather than as cumulative release, the mechanism underlying the week-3 clindamycin peak could not be determined, and scanning electron microscopy was qualitative without elemental confirmation of the observed deposits.

The clinical component was retrospective, single-centre and undertaken as a quality-improvement project. Although the association between catheter type and abdominal pain remained significant after adjustment for age, sex, primary diagnosis, mRS and activity level, residual confounding cannot be excluded. Furthermore, the clinical cohort reflected catheter systems in routine local use at the time and therefore did not include XABO® or DESU®. The clinical analysis cannot establish that any individual biochemical, mechanical or surface property identified in the laboratory caused abdominal symptoms.

Future work should include independent replication across larger numbers of samples and multiple manufacturing lots, with more extensive biochemical, mechanical and microbiological testing. Prospective multicentre studies with independent patient cohorts are required to determine whether the observed product-specific differences translate into clinically meaningful differences in infection, mechanical failure, abdominal symptoms, shunt longevity and patient-reported outcomes. Development of validated tools to capture the lived experience of patients with shunts should form part of this work. Future comparative work should also include DESU®, enabling a broader assessment of commercially available antibiotic-impregnated shunt systems using the same biochemical, mechanical and microbiological framework.

Conclusion

Commercially available antibiotic-impregnated shunt catheters demonstrated product-specific differences in antibiotic content, rifampicin integrity, elution profiles, antimicrobial activity, dimensions, mechanical properties and surface characteristics. XABO® most closely matched the nominal antibiotic content and retained the greatest proportion of intact rifampicin, while all three evaluated products maintained measurable antimicrobial activity against *Staphylococcus epidermidis* for 60 days. In the accompanying retrospective clinical analysis, catheter type was independently associated with otherwise unexplained abdominal pain after adjustment for

demographic and clinical factors. These findings are hypothesis-generating and do not establish causality, clinical non-equivalence or superiority of any one catheter. Prospective multicentre validation is required before catheter-specific properties can be used to guide individualised shunt selection.

Competing interests and in-kind support

The authors declare no competing interests. Ahmed K. Toma's academic activities are supported by the National Institute for Health and Care Research (NIHR) Biomedical Research Centre, however, the NIHR provided no funding or support for the present study.

Bactiseal®, Ares® and XABO® catheter samples were supplied in-kind support by their respective manufacturers. The manufacturers had no role in the study design, experimental conduct, data analysis, interpretation of results, manuscript preparation or decision to submit the work for publication. Delta Surgical was invited to provide DESU® catheter samples but declined participation.

Funding

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Keywords

Antibiotic-impregnated shunts; Bactiseal®; Ares®; XABO®; BASICS trial; hydrocephalus; ventriculoperitoneal shunt; shunt infection; abdominal pain.

Ethics statement and clinical governance

The laboratory component involved no human participants or animal, therefore, formal research ethics approval and informed consent were not required.

The retrospective clinical analysis was undertaken as a quality-improvement project approved and registered by the Trust's Quality and Safety team. No identifiable patient information is reported in this manuscript.

Data availability statement

The laboratory data supporting the findings of this study are available from the corresponding author on reasonable request. Access to the underlying clinical quality-improvement data is subject to applicable institutional governance and patient-confidentiality requirements. De-identified aggregate clinical data may be made available on reasonable request where permitted.

Author contributions

Dr Kanza Tariq was the principal investigator and contributed to study conception and design, data collection, data interpretation, and preparation of the manuscript.

Dr Mehran Moazen and Dr Anastasiia Maliuk performed the mechanical testing of the catheters and contributed to interpretation of the mechanical data.

Ms Celine Krista Vicedo, Mr Simon Thompson, Dr Jesvin Sunny, Mr Oliver Harper and Mr Ahmed K. Toma contributed to data collection and critical review of the manuscript.

Mr Lewis Thorne and Mr Laurence Watkins were the senior authors and contributed to study conception and design, manuscript preparation, and critical revision of the final manuscript.

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Supplementary material

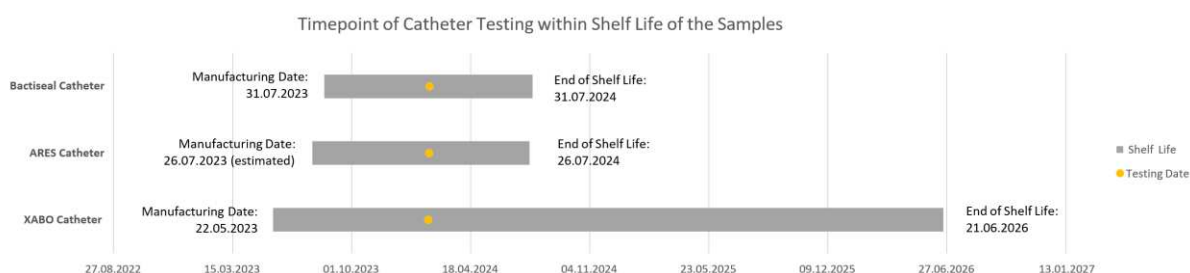


Figure 1. Timing of catheter testing relative to the manufacturer-specified shelf life of each sample. Grey bars represent the interval from manufacture to expiry, and yellow markers indicate the testing date.

Analyte	Ares® peritoneal (m%)	Ares® ventricular (m%)	XABO® peritoneal (m%)	XABO® ventricular (m%)	Bactiseal® peritoneal (m%)	Bactiseal® ventricular (m%)	Manufacturer-declared specification (m%)
Clindamycin hydrochloride	0.1408	0.1400	0.1368	0.1471	0.1291	0.1094	0.1500
Rifampicin	0.0381	0.0368	0.0510	0.0592	0.0401	0.0299	0.0540
Rifampicin quinone	0.0008	0.0012	0.0008	0.0010	0.0007	0.0008	Not specified
25-Desacetyl-rifampicin	0.0108	0.0114	0.0025	0.0021	0.0100	0.0080	Not specified
3-Formyl-rifampicin SV	0.0211	0.0189	< LOD	< LOD	0.0156	0.0147	Not specified

Table 1. Antibiotic load and rifampicin-related compounds identified in commercially available antibiotic-impregnated shunt catheters. Values are reported as mass percentage (m%). LOD, limit of detection. “< LOD” indicates that the analyte concentration was below the analytical detection limit.

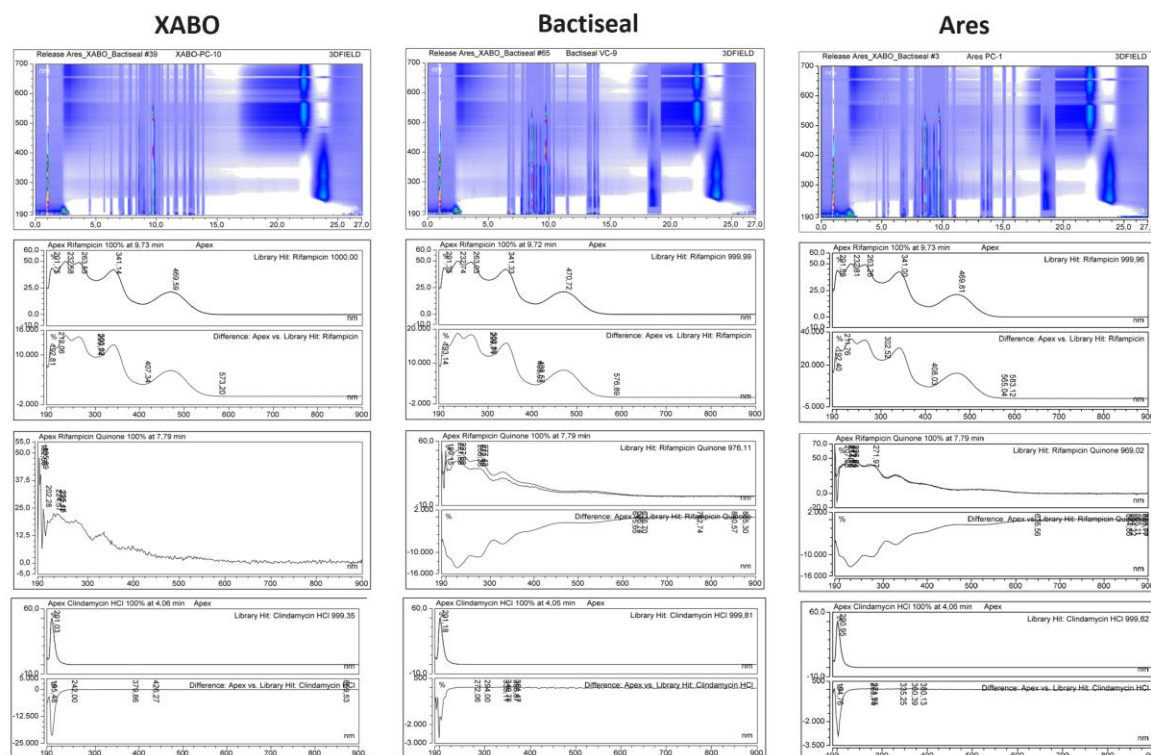


Figure 2. Comparative chromatographic profiles of antibiotic and rifampicin-related compounds in XABO®, Bactiseal®, and Ares® catheters.

Analyte (% of total peak area)	Ares® peritoneal	Ares® ventricular	XABO® peritoneal	XABO® ventricular	Bactiseal® peritoneal	Bactiseal® ventricular	Rifampicin EP standard
Intact rifampicin	50.86	49.08	89.77	85.24	59.12	54.23	96.96
Rifampicin quinone	1.53	2.67	1.19	1.36	1.32	1.98	0.83
25-Desacetyl-rifampicin	20.20	22.06	1.95	1.27	17.01	19.07	0.43
3-Formyl-rifampicin SV	25.44	23.40	< LOD	< LOD	< LOD	22.52	< LOD

Table 2. Rifampicin purity and relative abundance of rifampicin degradation products in antibiotic-impregnated shunt catheters. Values represent the percentage of total chromatographic peak area. EP, European Pharmacopoeia; LOD, limit of detection. “< LOD” indicates that the analyte was below the analytical detection limit.

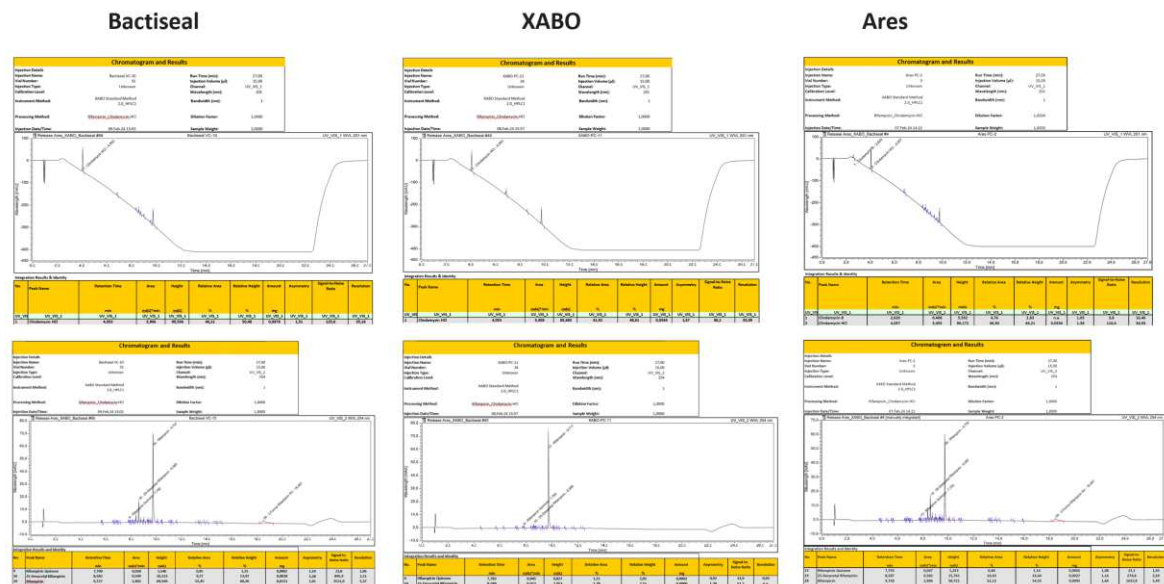


Figure 3. Comparative HPLC chromatograms and peak-area profiles of rifampicin, clindamycin, and rifampicin degradation products in Bactiseal®, XABO®, and Ares® catheter extracts.

Day	XABO® mean ± SD (mm)	Ares® mean ± SD (mm)	Bactiseal® mean ± SD (mm)
0	15.67 ± 0.29	14.43 ± 0.12	14.00 ± 0.00
2	14.00 ± 0.00	13.50 ± 0.00	13.33 ± 0.29
7	11.50 ± 0.00	11.20 ± 0.17	11.00 ± 0.00
14	10.33 ± 0.29	9.70 ± 0.00	9.17 ± 0.29
28	9.00 ± 0.00	8.50 ± 0.00	8.00 ± 0.00
38	7.00 ± 0.00	6.00 ± 0.00	5.50 ± 0.00
60	6.00 ± 0.00	5.00 ± 0.00	4.50 ± 0.00

Table 3. Mean inhibition-zone diameters for XABO®, Ares®, and Bactiseal® catheters against *Staphylococcus epidermidis* over 60 days. Values are presented as mean ± standard deviation (SD) from three replicate measurements at each time point. All measurements are reported in millimetres.

Duration of Study	Plate 1 Inhibition zone (mm)	Plate 2 Inhibition zone (mm)	Plate 3 Inhibition zone (mm)	Outcome	Duration of Study	Plate 1 Inhibition zone (mm)	Plate 2 Inhibition zone (mm)	Plate 3 Inhibition zone (mm)	Outcome	Duration of Study	Plate 1 Inhibition zone (mm)	Plate 2 Inhibition zone (mm)	Plate 3 Inhibition zone (mm)	Outcome
0d	15.5	15.5	16	Good effect	0d	14.5	14.5	14.3	Good effect	0d	14	14	14	Good effect
2d	14	14	14	Good effect	2d	13.5	13.5	13.5	Good effect	2d	13.5	13	13.5	Good effect
7d	11.5	11.5	11.5	Good effect	7d	11.3	11.3	11	Good effect	7d	11	11	11	Good effect
14d	10.5	10	10.5	Good effect	14d	9.7	9.7	9.7	Good effect	14d	9.5	9	9	Good effect
28d	9	9	9	Good effect	28d	8.5	8.5	8.5	Good effect	28d	8	8	8	Good effect
38d	7	7	7	Good effect	38d	6	6	6	Good effect	38d	5.5	5.5	5.5	Good effect
60d	6	6	6	Good effect	60d	5	5	5	Good effect	60d	4.5	4.5	4.5	Good effect

Measured inhibition zone for XABO catheter against test organism *S. epidermidis*

Measured inhibition zone for Ares catheter against test organism *S. epidermidis*

Measured inhibition zone for Bactiseal catheter against test organism *S. epidermidis*

Table 4. Inhibition-zone measurements for XABO®, Ares®, and Bactiseal® catheters against *Staphylococcus epidermidis* over 60 days.

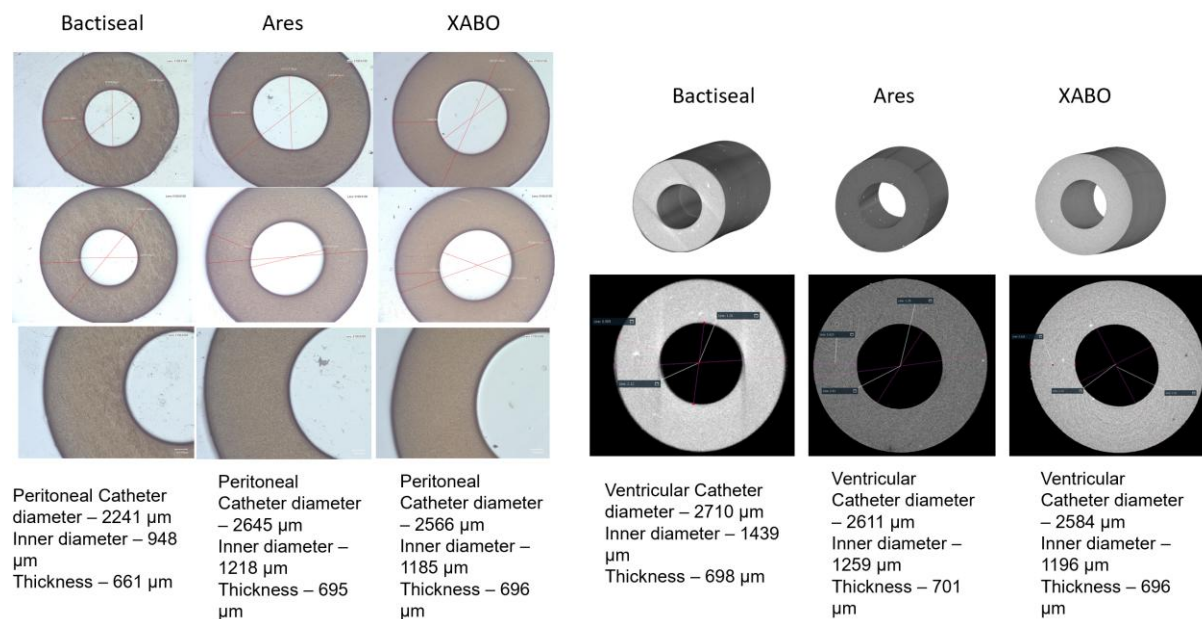


Figure 4. Three-dimensional computed tomography and dimensional analysis of the ventricular and peritoneal components of Bactiseal®, Ares®, and XABO® catheters.

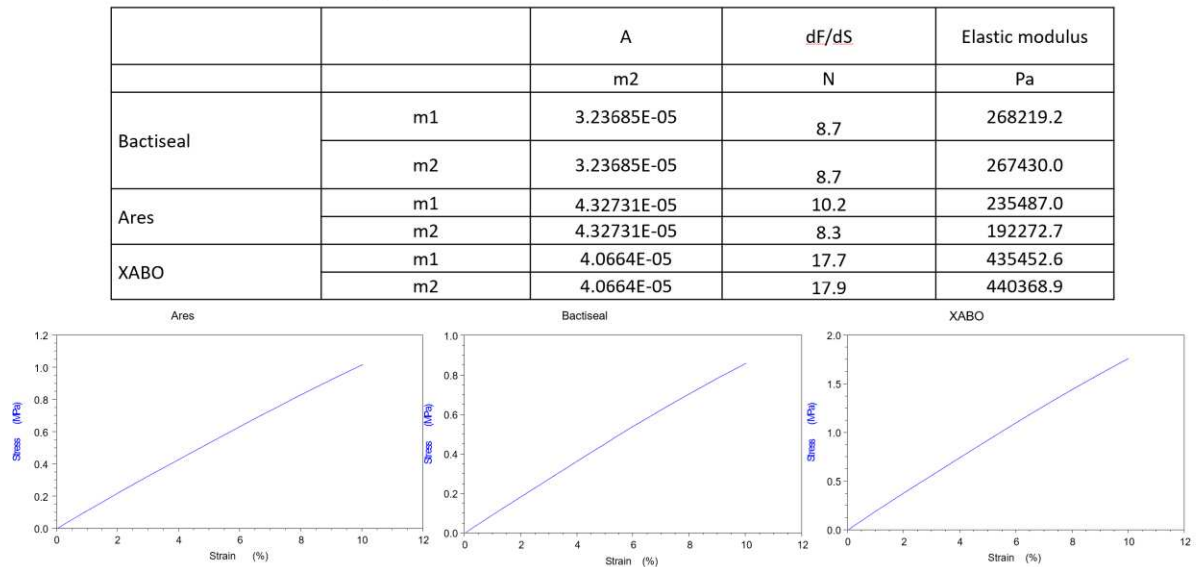
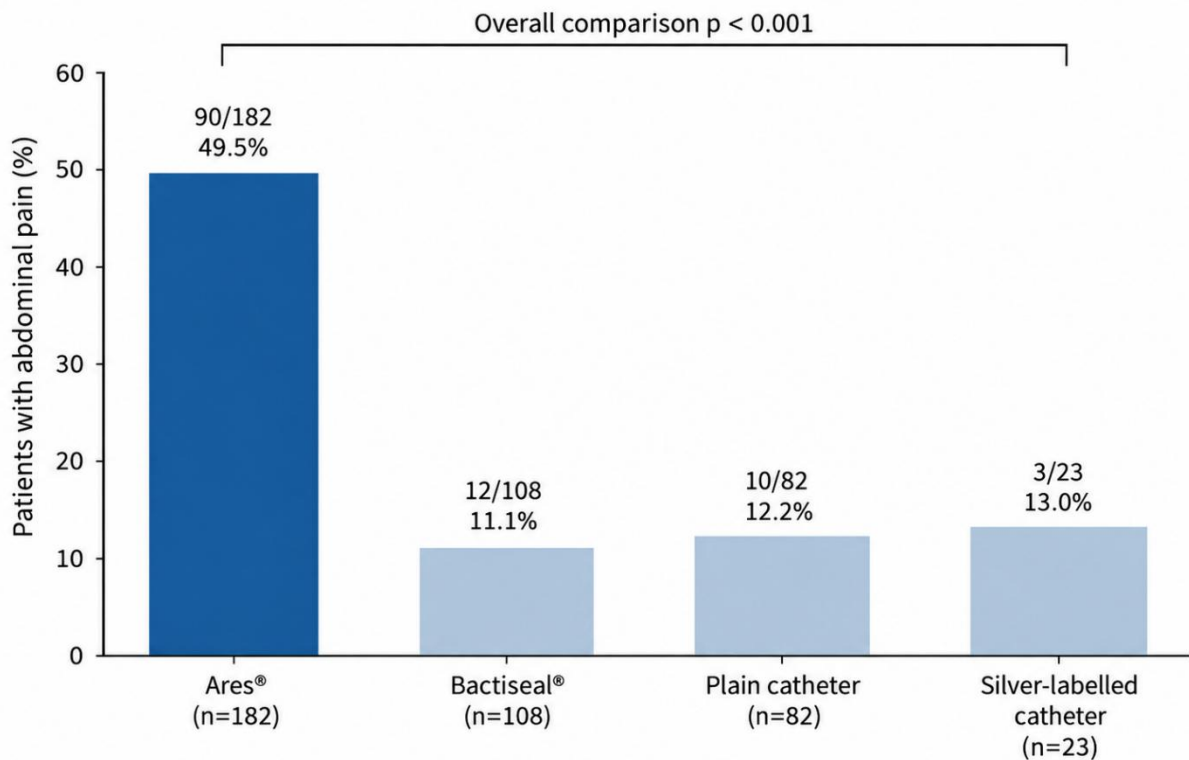


Figure 5. Elastic modulus and stress–strain profiles of Ares®, Bactiseal®, and XABO® peritoneal catheters assessed by nanoindentation. Higher elastic modulus indicates greater stiffness and lower deformability.

Incidence of documented abdominal pain by shunt catheter type



Retrospective single-centre quality-improvement cohort (n=395). Percentages are calculated within catheter type.

Figure 6. Incidence of documented abdominal pain by catheter type.

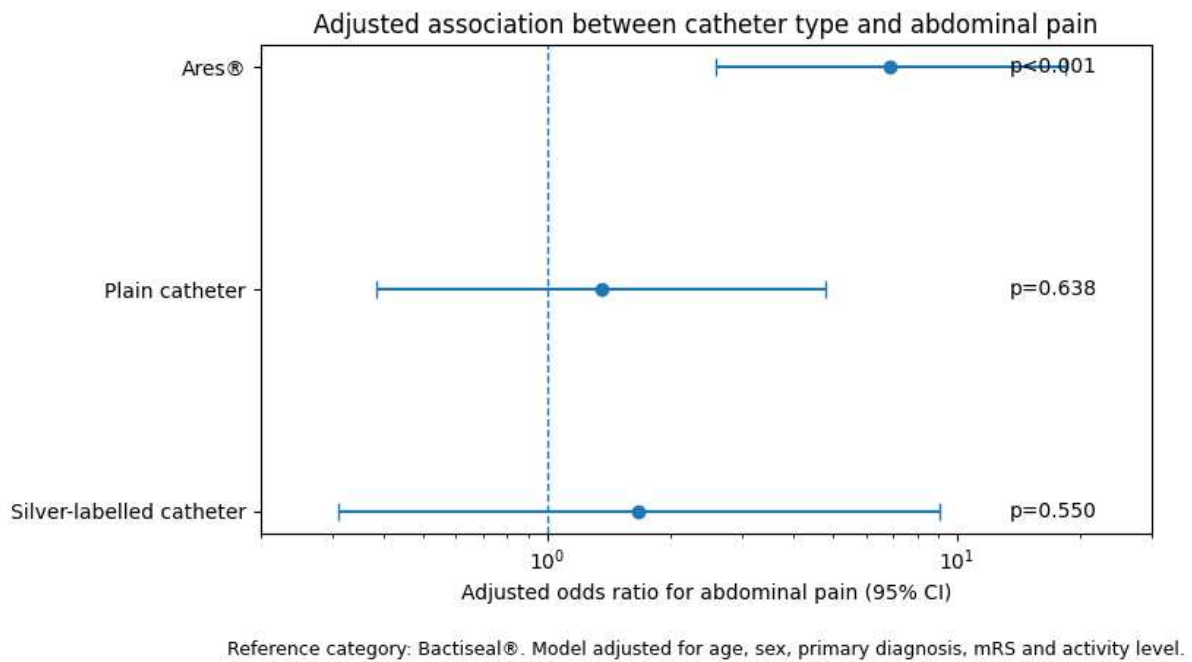


Figure 7. Adjusted association between shunt catheter type and otherwise unexplained abdominal pain. Forest plot showing adjusted odds ratios (ORs) and 95% confidence intervals derived from multivariable logistic regression. Bactiseal® was the reference category. The model was adjusted for age, sex, primary diagnosis, modified Rankin Scale score and activity level. The vertical dashed line denotes an OR of 1.0.