

ORIGINAL ARTICLE – OBSERVATION STUDY

Custom Made Candy Plug for Distal False Lumen Occlusion in Aortic Dissection: International Experience

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WHAT THIS PAPER ADDS

A custom made Candy Plug (CP) was used in 155 patients for distal false lumen occlusion in aortic dissection, with high technical and clinical success. Aortic remodelling and false lumen thrombosis rates were high. This study represents the first international experience with the CP technique. It confirms the excellent results from a previous large volume single centre study in a more real world setting including lower volume users. It confirms the relative ease of the CP technique, as a learning curve was not observed when comparing outcomes of high and low volume centres and early vs. late experiences within the high volume centres.

Objective: To evaluate early and midterm outcomes of the Candy Plug (CP) technique for distal false lumen (FL) occlusion in thoracic endovascular aortic repair for aortic dissection (AD) in a more real world cohort of patients from an international multicentre registry.

Methods: A multicentre retrospective study was conducted of all consecutive patients from the contributing centres with subacute and chronic AD treated with the CP technique from October 2013 to April 2020 at 18 centres.

Results: A custom made CP was used in 155 patients (92 males, mean age 62 ± 11 years). Fourteen (9%) presented with ruptured false lumen aneurysms. Technical success was achieved in all patients (100%). Clinical success was achieved in 138 patients (89%). The median hospital stay was 7 days (1 – 77). The 30 day mortality rate was 3% ($n = 5$). Stroke occurred in four patients (3%). Spinal cord ischaemia occurred in three patients (2%). The 30 day computed tomography angiogram (CTA) confirmed successful CP placement at the intended level in all patients. Early complete FL occlusion was achieved in 120 patients (77%). Early (30 day) CP related re-intervention was required in four patients (3%). The early (30 day) stent graft related re-intervention rate was 8% ($n = 12$). Follow up CTA was available in 142 patients (92%), with a median follow up of 23 months (6 – 87). Aneurysmal regression was achieved in 68 of 142 patients (47%); the aneurysm diameter remained stable in 69 of 142 patients (49%) and increased in five of 142 patients (4%). A higher rate of early FL occlusion was detected in the largest volume centre patients (50 [88%] vs. 70 [71%] from other centres; $p = .019$). No other differences in outcome were identified regarding volume of cases or learning curve.

Conclusion: This international CP technique experience confirmed its feasibility and low mortality and morbidity rates. Aortic remodelling and false lumen thrombosis rates were high and support the concept of distal FL occlusion in AD using the CP technique.

Keywords: Aneurysm, Aortic dissection, Aortic remodelling, Endovascular repair, False lumen occlusion, Thoracic endovascular aortic repair

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INTRODUCTION

Inducing false lumen (FL) thrombosis is crucial to achieving aortic remodelling when treating aneurysmal dilatation in chronic aortic dissection (AD).^{1,2} Retrograde FL perfusion after thoracic endovascular aortic repair (TEVAR) is one of the pitfalls of TEVAR potentially preventing remodelling in chronic AD.^{3,4} To overcome this problem of FL patency, studies have described different strategies, including direct FL occlusion techniques like the “Cork in the bottle neck” strategy by Loubert *et al.*⁵ and more indirect strategies using fenestrated and branched endovascular aortic repair (F/B-EVAR), with increased aortic coverage and its inherent risks of endoleak and spinal cord ischaemia.^{6,7}

Direct embolisation techniques of the distal thoracic FL through coils, plugs, glue, and iliac occluder have shown an acceptable aortic remodelling rate, but also a high rate of further re-interventions,^{8–11} however, these materials cannot be applied for large FL diameters.¹²

Kölbl *et al.* initially described the Candy Plug (CP) technique as a two step procedure involving modifying a thoracic stent graft and closing the diameter reduced waist with an additional plug.¹³ Since then, three device generations of the CP (Cook Medical, Bloomington, IN, USA) have been introduced and a high rate of technical and clinical success accompanied by aortic remodelling has been reported at early and midterm follow up from a single centre.^{14–17} Numerous international vascular centres have adopted the technique.^{14–17}

This study aimed to evaluate the overall international early and midterm outcomes of the CP technique for distal FL occlusion in TEVAR for AD in a real world cohort of patients. It compared both higher and lower volume centres and early vs. late experiences.

METHODS

A multicentre retrospective study was conducted including all consecutive patients from the contributing centres who received a custom made CP device to embolise the distal false lumen in subacute and chronic AD from October 2013 to April 2020 at 18 centres. The contribution by centre is shown in Table 1. The contributing centres did not differ in their general treatment indications with ruptured FL aneurysm, FL aneurysm > 5.5 cm, or rapid diameter progression (> 5 mm in six months).¹ The design of the CP generations and its planning and implantation techniques have been described previously.^{15–17} The computed tomography angiography (CTA) follow up was performed according to the centres’ standards and generally included studies at one, six, and 12 months and yearly thereafter. All patients consented for clinical research. Due to the retrospective analysis of the anonymised data, approval from the local ethics committee was waived.

Definitions and endpoints

Subacute and chronic AD were defined as between 15 – 90 days and > 90 days after the initial event, respectively.¹⁸ Urgency was defined as symptomatic aneurysm (thoracic pain) and \geq 8 cm diameter. Emergency was defined as ruptured false lumen aneurysm.

Table 1. Contributing centres

| Institution | Patients included |
|---|-------------------|
| German Aortic Centre, Hamburg, Germany | 57 |
| Hospital Marie Lannelongue, Paris, France | 23 |
| San Raffaele Hospital, Milan, Italy | 19 |
| Skåne University Hospital, Malmö, Sweden | 9 |
| CHU (Centre Hospitalo-Universitaire), Lille, France | 6 |
| University Hospital, LMU, Munich, Germany | 6 |
| Klinikum Passau, Passau, Germany | 6 |
| University Hospital Carl Gustav Carus, Dresden, Germany | 5 |
| Università degli Studi di Milano, Milan, Italy | 5 |
| Leiden University Medical Centre, Leiden, The Netherlands | 4 |
| University of Regensburg, Regensburg, Germany | 4 |
| Monaco Cardio-Thoracic Centre (CCM), Monaco, France | 3 |
| University Health Network, Toronto, Canada | 2 |
| University Medical Centre Groningen, Groningen, The Netherlands | 2 |
| The University of Hong Kong, Hong Kong | 1 |
| Medical University of Warsaw, Warsaw, Poland | 1 |
| Helios Weißeritztal Clinics, Dresden, Germany | 1 |
| St Thomas’ Hospital, London, United Kingdom | 1 |

Data are shown as *n*

Endpoints included technical, clinical success, and early (30 day) CTA findings. Technical success was defined as correct placement of the true lumen stent graft and the CP at the intended level in the FL. Clinical success was defined as prevention of FL backflow at the CP level on final angiography. Early (30 day) CTA findings included the correct placement of the CP with no FL backflow beyond the CP. Other endpoints were early (30 day) death, adverse events, and aortic remodelling in patients with available CTA follow up. Aortic remodelling was based on the largest thoracic perpendicular aortic diameter including false and true lumens on the first post-operative CT scan compared with the most recent CT scan. The definition of aneurysm sac enlargement or shrinkage was an increase or decrease in diameter > 5 mm.¹⁸ A decrease > 5 mm in aortic diameter was defined as regression, and diameter changes \leq 5 mm were considered as stable.

Re-interventions were divided into CP related re-interventions to achieve complete FL sealing of the CP and TEVAR related re-interventions that were related to the true lumen (TL) stent graft like Type IA endoleak treatment.

Technical feasibility, clinical success, early death, early complete FL occlusion, early CP related re-interventions, and aortic remodelling during follow up were analysed and compared according to the centres’ volume. High volume centres (Hamburg, Paris, and San Raffaele Hospital Milan) with a total of 99 patients were compared with low volume centres with a total of 56 patients. Another analysis was conducted comparing the largest centres’ results vs. all other centres.

The learning curve was assessed by comparing the early experience (first 10 cases) with the late experience (the

Table 2. Patient characteristics and comorbidities of 155 patients with Candy Plug

| Variables | Patients (n = 155) |
|--|-----------------------|
| <i>Demographics</i> | |
| Age – years | 62±11 |
| Male gender | 92 (59) |
| <i>Cardiovascular risk factors</i> | |
| Hypertension | 146 (94) |
| Cigarette smoking | 55 (40) |
| Hypercholesterolaemia | 39 (25) |
| Renal insufficiency | 21 (14) |
| Coronary artery disease | 18 (12) |
| Chronic obstructive pulmonary disease | 17 (11) |
| Active smoking | 15 (10) |
| Stroke or transient ischaemic attack | 10 (7)/3 (2) |
| Genetic aortic syndrome | 8 (5) |
| Diabetes mellitus | 6 (4) |
| Myocardial infarction | 3 (2) |
| Peripheral arterial disease | 3 (2) |
| <i>Any previous aortic repair</i> | |
| Aortic root or arch repair | 76 (49) |
| Thoracic endovascular aortic repair | 48 (31) |
| Combined open and endovascular arch repair | 12 (8) |
| Endovascular aortic arch repair | 7 (5) |

Data are presented as n (%) or mean ± standard deviation.

latest 69 patients) of the high volume centres (Hamburg, Paris, and San Raffaele Hospital Milan).

Technical feasibility, clinical success, early death, early complete FL occlusion, early CP related re-interventions, and aortic remodelling during follow up were analysed for the 14 emergency patients with a ruptured FL.

Numerical data were expressed as median and range. Categorical data were expressed as absolute numbers and percent prevalence (%) in the study cohort. Statistical analysis was performed using IBM SPSS Statistics for Macintosh (version 22.0; IBM Corporation, Somers, NY, USA).

RESULTS

A custom made Candy Plug was used in 155 patients (92 males, mean age 62 ± 11 years). Of these, 65 patients (42%) were treated with CP I, 53 patients (34%) with CP II, and 37 patients (24%) with CP III, respectively. Table 2 summarises patient characteristics and comorbidities. Residual type A AD (TAAD) and type B AD accounted for 85 patients (55%) and 70 patients (45%), respectively. The median maximum aortic aneurysm diameter was 61 mm (38 – 111). One hundred and forty-three patients (92%) had undergone previous proximal aortic repair.

One hundred and twenty-three patients (79%) presented with elective conditions. Eighteen patients (12%) presented with urgent conditions. Fourteen patients (9%) presented with ruptured false lumen aneurysms. Table 3 illustrates the anatomical, pathological criteria, and status of the aortic aneurysm of all patients with CP. Left common carotid artery to left subclavian artery bypass was performed for 82 patients (53%). Of these, 21 of 82 bypasses were

Table 3. Anatomical, pathological criteria, and status of aortic aneurysm of 155 patients with Candy Plug

| Variables | Patients (n = 155) |
|-------------------------------|-----------------------|
| Type A AD | 85 (55) |
| Type B AD | 70 (45) |
| Subacute AD | 17 (11) |
| Chronic AD | 138 (89) |
| Maximum aortic diameter | 61±12 |
| <i>Status of the aneurysm</i> | |
| Elective | 123 (79) |
| Urgent | 18 (12) |
| Emergent | 14 (9) |

Data are presented as n (%) or mean ± standard deviation.

AD = aortic dissection.

simultaneous, 59 of 82 bypasses were pre-operative, and two of 82 bypasses were post-operative. Central lumen occlusion in CP I was performed using a 20 mm Iliac ZIP occluder (Cook Medical, Bjaeverskov, Denmark) and a 22 mm Amplatzer vascular plug (St. Jude Medical, St. Paul, MN, USA) in 33 of 65 patients (51%) and 32 of 65 patients (49%), respectively. CP II and CP III have a self occluding sleeve and do not require occlusion of the central channel, thus simplifying the procedure.

Technical success was achieved in all patients. Clinical success was achieved in 138 patients (89%). The median hospital stay was 7 days (1 – 77). The length of hospital stay was generally not related to the CP procedure but to the complexity of the proximal repair. Table 4 summarises the procedural details. The 30 day mortality rate was 3% (n = 5). Causes of death were stroke, respiratory failure with sepsis, sudden cardiac arrest, retrograde TAAD, and cardiac failure with pulmonary oedema; retrograde TAAD occurred in three patients (2%).

Early complete thoracic FL thrombosis was achieved in 120 patients (77%), according to the early post-operative CTA. Early CP related re-interventions were required in four patients (3%); all required coil embolisation due to retrograde flow beside the CP.

The early stent graft related re-intervention rate was 8% (n = 12). Re-interventions included: 1) open repair of retrograde TAAD in three patients, of which one patient died early after the open repair; 2) frozen elephant trunk repair for type IA endoleak in two patients; 3) proximal extension of the stent graft to cover the left subclavian artery (LSA) with a left common carotid artery (CCA) to LSA bypass to seal a type IA endoleak in one patient, extension of a bridging covered stent to the brachiocephalic artery to seal type IC endoleak in one patient; 4) relining of the true lumen stent graft in three patients due to kinks in two patients and infolding in one; 5) right CCA to left CCA bypass for focal dissection; and 6) revision of a left CCA to LSA bypass.

Distal aortic extension with fenestrated or branched stent grafts during follow up due to development of an abdominal false lumen aneurysm was performed in seven patients (5%); four patients were originally planned for F/B-TEVAR as a second stage, one patient was treated for a ruptured

| Variables | Patients (n = 155) |
|--|-----------------------|
| Primary CP | 127 (82) |
| <i>Type of stent graft TEVAR in primary CP</i> | |
| Standard stent graft | 76 (49) |
| Fenestrated stent graft | 17 (11) |
| Branched stent graft | 34 (22) |
| LCCA-LSA bypass | 82 (53) |
| False lumen backflow beyond level of CP on final angiogram | 17 (11) |
| Technical success | 155 (100) |
| Clinical success | 138 (89) |
| Total operating time – minutes | 214±56 |
| Total fluoroscopy time – minutes | 32±23 |
| Amount of contrast used – mL | 139±67 |
| Dose Area Product – Gy.cm2 | 345±443 |
| Hospital stay – days | 11±10 |

Data are presented as n (%) or mean ± standard deviation.

CP = Candy Plug; TEVAR = thoracic endovascular aortic repair; LCCA = left common carotid artery; LSA = left subclavian artery.

TAAA, and two patients developed an enlarged abdominal FL during follow up. Table 5 summarises the early mortality and morbidity and the early and follow up CTA results. Follow up CTA was available in 142 patients (92%) with a median follow up of 23 months (6 – 87). The post-operative median maximum aortic aneurysm diameter was 54 mm (38 – 90 mm). The thoracic aortic aneurysm was remodelled in 68 of 142 patients (47%) and its size remained stable in 69 of 142 patients (49%). The thoracic aortic aneurysm size increased in five of 142 patients (4%).

There was no statistically significant difference between the high and low volume centres regarding the technical feasibility, clinical success, early outcome, and follow up aortic remodelling (Table 6). Comparing the early and late experience in high volume centres demonstrated no statistically significant differences (Table 7). Comparing the largest centres' outcome with other centres' outcome (Table 8) showed a higher rate of early FL occlusion (50 (88%) vs. 70 patients (71%); $p = .019$). No other statistically significant difference was detected.

In the emergency group (14 patients), TEVAR and primary CP were performed in 10 cases, while a previous TEVAR in the true lumen had been performed in four cases. Seven, four, and three patients received a CP I, II, and III, respectively. Technical success was achieved in 14 patients and clinical success in 10 of 14 patients. Thirty day mortality in emergency cases was four patients (28.6%). Early respiratory complications occurred in three of 14 patients. Early renal insufficiency that required dialysis occurred in two of 14 patients. Early complete thoracic FL occlusion was achieved in nine of 10 patients, who survived, according to the early post-operative CTA. Early CP related re-interventions were required in one patient (of 14), who required additional coil embolisation.

Follow up CTA was available in 10 of 14 patients. The thoracic aortic aneurysm was remodelled in four of 10

| Variables | Patients (n = 155) |
|--------------------------------------|-----------------------|
| Early death | 5 (3) |
| <i>Early adverse events</i> | |
| Stroke or transient ischaemic attack | 4 (3) |
| Spinal cord ischaemia | 3 (2) |
| Renal insufficiency | 5 (3) |
| <i>With dialysis</i> | 2 (1) |
| <i>No dialysis</i> | 3 (2) |
| Respiratory complications | 7 (5) |
| Cardiac complications | 4 (3) |
| Retrograde type A aortic dissection | 3 (2) |
| Wound complications | 8 (5) |
| Vascular access complications | 2 (1) |
| Other minors | 10 (7) |
| Early complete FL occlusion (CTA) | 120 (77) |
| <i>Early re-intervention</i> | |
| Candy Plug related | 4 (3) |
| Aortic stent graft related | 12 (8) |
| Other minors | 9 (6) |
| <i>Follow up CTA</i> | |
| Remodelling of aneurysm sac | 68/142 (47) |
| Stable aneurysm sac | 69/142 (49) |
| Increase of aneurysm sac | 5/142 (4) |

Data are presented as n (%). CTA = computed tomography angiography.

| Variables | High volume centres (n = 99) | Low volume centres (n = 56) | p value |
|--|---------------------------------|--------------------------------|---------|
| Technical success | 99 (100) | 56 (100) | .96 |
| Clinical success | 93 (94) | 45 (80) | .23 |
| Early death | 3 (3) | 2 (4) | .16 |
| Early complete false lumen occlusion (CTA) | 76 (77) | 44 (79) | .59 |
| Early CP related re-intervention | 3 (3) | 1 (2) | .16 |
| <i>Follow up CTA</i> | | | |
| Remodelling of aneurysm sac | 52/86 (60) | 16/56 (29) | .20 |
| Stable aneurysm sac | 32/86 (37) | 37/56 (66) | .17 |
| Increase of aneurysm sac | 2/86 (2) | 3/56 (5) | .87 |

Data are presented as n (%). CTA = computed tomography angiography; CP = Candy Plug.

patients. The size remained stable in five of 10 patients and increased in one patient.

DISCUSSION

Retrograde FL perfusion is the Achilles heel of TEVAR in patients with chronic AD.^{1,17} To overcome this problem, the CP technique was introduced to achieve FL occlusion with a high rate of technical and clinical success and aortic remodelling.^{14–17}

The current study confirms previous results in a real world experience with a larger patient number and more

Table 7. Assessment of learning curve by comparing early experience with late experience in high volume centres

| Variables | Early experience in high volume centres (n = 30) | Late experience in high volume centres (n = 69) | p value |
|--|--|---|---------|
| Technical success | 30 (100) | 69 (100) | .97 |
| Clinical success | 28 (93) | 65 (94) | .45 |
| Early death | 2 (7) | 1 (1) | .16 |
| Early complete false lumen occlusion (CTA) | 23 (77) | 53 (77) | .53 |
| Early CP related re-intervention | 2 (7) | 1 (1) | .17 |
| Follow up CTA | 30 (100) | 56 (81) | |
| Remodelling of aneurysm sac | 17/30 (57) | 35/56 (63) | .52 |
| Stable aneurysm sac | 12/30 (40) | 20/56 (36) | .85 |
| Increase of aneurysm sac | 1/30 (3) | 1/56 (2) | .93 |

Data are presented as n (%). CTA = computed tomography angiography; CP = Candy Plug.

Table 8. Outcome of Hamburg centre vs. other centres

| Variables | Hamburg centre (n = 57) | Other centres (n = 98) | p value |
|--|-------------------------|------------------------|---------|
| Technical success | 57 (100) | 98 (100) | .49 |
| Clinical success | 54 (95) | 84 (86) | .74 |
| Early death | 2 (4) | 3 (3) | .38 |
| Early complete false lumen occlusion (CTA) | 50 (88) | 70 (71) | .019 |
| Early CP related re-intervention | 3 (5) | 1 (1) | .37 |
| Follow up CTA | 44 (77) | 98 (100) | |
| Remodelling of aneurysm sac | 27/44 (61) | 41/98 (42) | .18 |
| Stable aneurysm sac | 16/44 (36) | 53/98 (54) | .088 |
| Increase of aneurysm sac | 1/44 (2) | 4/98 (4) | 1.0 |

Data are presented as n (%). CTA = computed tomography angiography; CP = Candy Plug.

participating centres. The favourable aortic remodelling at midterm follow up supports the underlying need for distal FL occlusion in chronic AD. Achieving complete FL thrombosis with remodelling has a proven benefit for the prognosis of chronic AD. Morbidity and mortality rates of the CP technique were low and not directly related to the CP technique itself but rather to the accompanying TEVAR procedure.

Fenestrated and branched EVAR is an alternative technique to treat or prevent retrograde FL perfusion in chronic AD but carries a higher risk of major adverse events due to its increased complexity and aortic coverage.^{6,7,19} In four patients, who initially presented with additional abdominal FL enlargement, the CP served as a bridging procedure to close the large thoracic FL aneurysm in advance of a later distal extension, which had an impact on the development of the spinal cord blood flow network and protected them from spinal cord ischaemia.

Alternative techniques to embolise the distal FL have been described using a large variety of materials, but generally appear more difficult, time consuming, and associated with lower technical and clinical success rates compared with the CP technique of 60 – 90%.^{9,20–23} The main limitation of alternative embolisation techniques is the treatable diameter of the FL, as commercially available occluders and coils are unavailable in diameters > 24 mm, while the largest diameter of the CP is currently 46 mm.^{17,19–24} The theory behind the distal alignment of the true and FL stent grafts is to protect the dissection

membrane against radial forces and avoid new stent graft induced entry tears.⁸

This study did not observe a learning curve, with comparable outcomes in high and low volume centres and when comparing outcomes of early and late experiences within the high volume centres, which can be explained by the relatively straightforward CP technique. A further analysis to compare the outcome in Hamburg with other centres showed a higher rate of early FL occlusion in the Hamburg group. There were no further significant differences between centres.

The high mortality and morbidity of emergency patients was related to the haemodynamic instability of this group of patients. However, CP was effective in most cases and achieved a high rate of false lumen thrombosis and aortic remodelling.

One limitation of the CP technique is the custom made device technology, which is not available in emergency situations. However, several techniques to modify standard TEVAR devices to create a physician modified CP have been described with effective distal FL occlusion.^{25–27}

Limitations

This study had several limitations, including the shortcomings due to its retrospective non-controlled nature with a heterogeneous technical experience in the contributing centres and absence of a comparison group. Another limitation was that approximately 8% of patients was lost during follow up; this was due to the short time since the

application of the second and third generation of CP. Another reason for lost to follow up was that high volume centres receive patients from far away and who frequently prefer to be followed up locally. No core lab analysis of imaging was conducted. The diameters of CP and FL at the site of CP implantation were not assessed. The type of TEVAR stent graft and the effect of the radial force of CP over low profile stent grafts were not included in the analysis. Furthermore, this study did not examine the impact of the number of aortic side branches originating from the FL or the role of anticoagulation on FL thrombosis.²⁸

An international registry with regular updates is required to validate the impact of the CP technique on aortic remodelling over the long term and compared with different generations of the CP device.

Conclusion

This international experience with the CP technique confirms its technical feasibility, and low mortality and morbidity rates. Aortic remodelling and FL thrombosis rates are high and support the concept of distal FL occlusion as an important adjunct to the care of AD.

CONFLICTS OF INTEREST

Tilo Kölbel has intellectual property with Cook Medical, receives royalties, research, travel and educational grants, speaking fees, and is consultant and proctor with Cook Medical. Stephan Haulon is a consultant for Cook Medical, GE Healthcare, and Bentley. Luca Bertoglio is a proctor and consultant for Cook Medical. Santi Trimarchi is a consultant and speaker for WL Gore and Medtronic. Thomas Lindsay is a proctor and consultant with Cook Canada. Tomasz Jakimowicz has travel grants, consultation fees, and proctorship fees from Cook Medical and Hammered (Polish representative of Cook Medical). Jonathan Sobocinski is a speaker, proctor, and consultant with Cook Medical. Nikolaos Tsilimparis is a proctor for Cook Medical and receives an institutional grant from Cook Medical. Giuseppe Panuccio is a proctor with Cook Medical.

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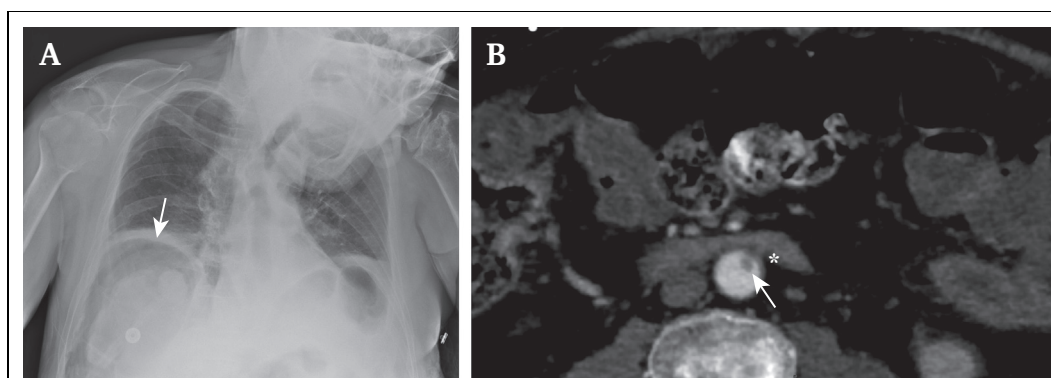
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COUP D’OEIL

Embolic Occlusion of the Inferior Mesenteric Artery Is a Cause of Ischaemic Colitis

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A 66 year old male with acute lower limb ischaemia Rutherford IIA, due to femoroperoneal bypass thrombosis, was treated by catheter directed thrombolysis using a crossover 8 French sheath with low dose heparin. Despite 48 hours of thrombolysis, and a novel attempt at endovascular recanalisation, the bypass remained occluded. Meanwhile, the patient experienced respiratory failure. The chest Xray revealed a pneumoperitoneum (A, arrow). This was caused by grade III ischaemic colitis and confirmed by computed tomography angiography also noting an inferior mesenteric artery occlusion caused by an aortic thrombus (B, asterisk, arrow). He underwent a Hartmann procedure, and later transfemoral amputation.

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