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The Impact of Initial Misdiagnosis of Ruptured Abdominal Aortic Aneurysms on Lead Times, Complication Rate, and Survival

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WHAT THIS PAPER ADDS

This study provides data on the frequency of initial misdiagnosis in patients treated for ruptured abdominal aortic aneurysms and the clinical consequences of misdiagnosis in terms of adjusted mortality and post-operative care.

Objective/Background: To investigate the frequency of initial misdiagnosis and the clinical consequences of an initial misdiagnosis of ruptured abdominal aortic aneurysms (rAAA).
Methods: This was a retrospective cohort study. Data from the Swedish National Registry for Vascular Surgery (Swedvasc) and medical charts were extracted for patients treated for rAAA in the West of Sweden in the period 2008–14. Initially misdiagnosed patients were compared with correctly diagnosed patients.
Results: In all, 261 patients were included in the study. Patients with rAAA were initially misdiagnosed in 33% ($n = 86$) of the cases and this caused a 4.8 hour (median time) additional delay to surgical intervention. There were no differences in 30 day mortality between initially misdiagnosed patients and correctly diagnosed patients (27.9% vs. 28.0%; $p = 1.00$). The adjusted odds ratio for mortality in initially misdiagnosed patients compared with correctly diagnosed patients was 0.78 (95% confidence interval 0.38–1.60). No difference was observed between the groups regarding 90 day mortality, length of intensive care, need for post-operative ventilator support, need of haemodialysis support, and length of hospital stay.
Conclusion: Misdiagnosis is common in patients with rAAA, and treatment is significantly delayed in misdiagnosed patients. The study did not show any survival disadvantage or increased frequency of post-operative complications in misdiagnosed patients despite the delayed treatment. However, only patients who reached surgical intervention were included in the analysis.

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INTRODUCTION

Ruptured abdominal aortic aneurysms (rAAA) have an annual mortality rate of around 150,000 individuals worldwide.[1] The overall prognosis remains poor with a total mortality of around 70% reported in later studies,[2–4] despite advances in modern health care. Although theoretically appealing, randomised trials have failed to demonstrate robust evidence of any survival advantage for endovascular aortic repair (EVAR) compared with open surgical repair (OSR) in patients with rAAA.[5–8] Screening programs have been proven to reduce aneurysm related mortality substantially by identifying AAAs before rupture, allowing for surgical intervention in an elective setting.[9–11] However, as screening programs currently have a very limited coverage throughout the world and will always have non-attenders, the treatment of rAAAs will continue to pose a significant clinical challenge.

An observation made by many surgeons and also described in previous studies is that rAAAs are frequently misdiagnosed in the acute setting.[12–23] Although it is known that misdiagnosis is common in patients with rAAA, the clinical consequences of a misdiagnosis in terms of the patient's prognosis are largely unknown.

It was hypothesized that both the mortality rate and post-operative complications are more frequent in patients treated for rAAA if they are initially misdiagnosed. The aim of this study was to investigate the frequency of misdiagnosis and the clinical consequences of a misdiagnosis of rAAA in terms of treatment and outcome.

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METHODS

Study design

The study was a retrospective cohort study comparing the outcome in two cohorts of patients that were treated for a rAAA: those who were correctly diagnosed at the first clinical assessment by a physician in the emergency department (ED), and those who were initially misdiagnosed. The primary endpoint was 30 day mortality. Secondary endpoints were 90 day mortality, need for post-operative haemodialysis, need for ventilator support, days in the intensive care unit (ICU), and length of hospital stay.

Setting and participants

Patients admitted to any of the 11 EDs within the healthcare organisation in the West of Sweden (Västra Götaland Region) who were subsequently treated by EVAR or OSR for a rAAA from May 2008 to December 2014 were eligible for inclusion.

EDs in the region are generally staffed with residents, with specialists/consultants available on demand. One of the participating hospitals has an ED staffed by an emergency medicine clinic. The other 10 hospitals have EDs staffed by the surgical clinic, the internal medicine clinic, and the orthopaedic clinic together.

Data regarding age, sex, comorbidities, and type of procedure, and peri-operative data were extracted from the Swedish National Registry for Vascular Surgery (Swedvasc). The definition of comorbidities reported in Swedvasc are: *cardiac disease*, history of coronary heart disease or congestive heart failure; *hypertension*, hypertension with medical treatment; *pulmonary disease*, chronic obstructive pulmonary disease or emphysema or other chronic pulmonary disease with symptoms; *previous TIA/stroke*, previous transient ischaemic attack, ischaemic or haemorrhagic stroke.

Data regarding the assessment and treatment during the pre-hospital phase and within the ED, as well as treatment chain time parameters, were extracted from electronic medical charts. The first registered blood pressure (BP) was the first BP recorded by paramedics in the pre-hospital phase for ambulance transported patients and the first BP recorded in the ED for ambulatory patients.

Patients without a Swedish personal identity number were excluded (owing to lack of reliable mortality data), as were thoracic, thoraco-abdominal, and mycotic aneurysms. Patients who were registered as treated for a rAAA in Swedvasc, but on review of the medical charts were found not to have a rAAA or a ruptured iliac aneurysm, and who were thus misclassified in the registry, were excluded. Patients lacking a medical chart from the ED were also excluded (Fig. 1).

Patients with rupture of an AAA during a hospital stay for another condition or after admission for elective treatment of an AAA were excluded as the primary aim of the study was to evaluate the clinical consequences of a misdiagnosis in the ED. To minimise the risk of excluding patients admitted to a hospital ward for treatment of another condition because of a misdiagnosed rAAA in the ED the medical charts of those patients were thoroughly reviewed by two separate reviewers.

Patients were classified as having a *correct diagnosis* at the first assessment in the ED if one or more of the following criteria were fulfilled: (i) aortic aneurysm was mentioned as the primary preliminary diagnosis or a differential diagnosis in the note in the medical chart made by the first physician assessing the patient in the ED; (ii) the patient was referred from the ED for an acute computed tomography scan of the abdomen or aorta, with the words "aortic aneurysm" mentioned in the question to the radiologist; (iii) the patient was taken immediately to theatre for laparotomy for suspected rAAA. Patients who did not fulfill any of the three criteria were classified as having a *misdiagnosis* at the preliminary assessment in the ED.

Patients correctly diagnosed with rAAA at the first assessment in the ED were compared with patients who were initially misdiagnosed regarding comorbidities, time from admission to start of the operative procedure, mortality, need for post-operative haemodialysis, need for ventilator support, days in the ICU, and length of hospital stay.

Ethical approval for the project was obtained from the Regional Ethical Review board in Gothenburg (Dnr 553-14).

The Swedvasc registry

Swedvasc is Sweden's National Quality Registry for Vascular Procedures. The registry has had national coverage since 1994 and includes all vascular centres in Sweden. For all aortic procedures, vascular surgeons or interventional radiologists prospectively register peri-procedural data, patient data, including risk factors, and complications within 30 days. The registry is interconnected with the Swedish Cause of Death Registry and thereby provides reliable mortality data for all registered patients. Swedvasc has proven to be a highly accurate system for collecting data on Swedish vascular surgery with an external validity exceeding 93%.[24,25]

Statistics

All statistical analysis was performed in IBM SPSS statistics 23.0. Descriptive statistics are presented for demographic and baseline variables as mean $\pm$ SD and absolute and relative frequencies. Fisher's exact test was used for intergroup comparisons of dichotomous variables. Student *t* test was used for the comparison of means. The Mann—Whitney test was used for non-normal continuous variables. Binary logistic regression was used to analyse possible confounding factors influencing 30 day mortality. Univariate regression was performed followed by multivariate regression analysis. Misdiagnosis/correct diagnosis, age, sex, type of procedure (EVAR or OSR), and transportation to secondary hospital was a priori introduced to the adjusted model. Significant risk factors in the univariate analysis were introduced to the adjusted model. A two sided *p* value $< .05$ was considered to be significant.

RESULTS

In all, 261 patients were included in the study. A flowchart of patient selection is shown in Fig. 1.

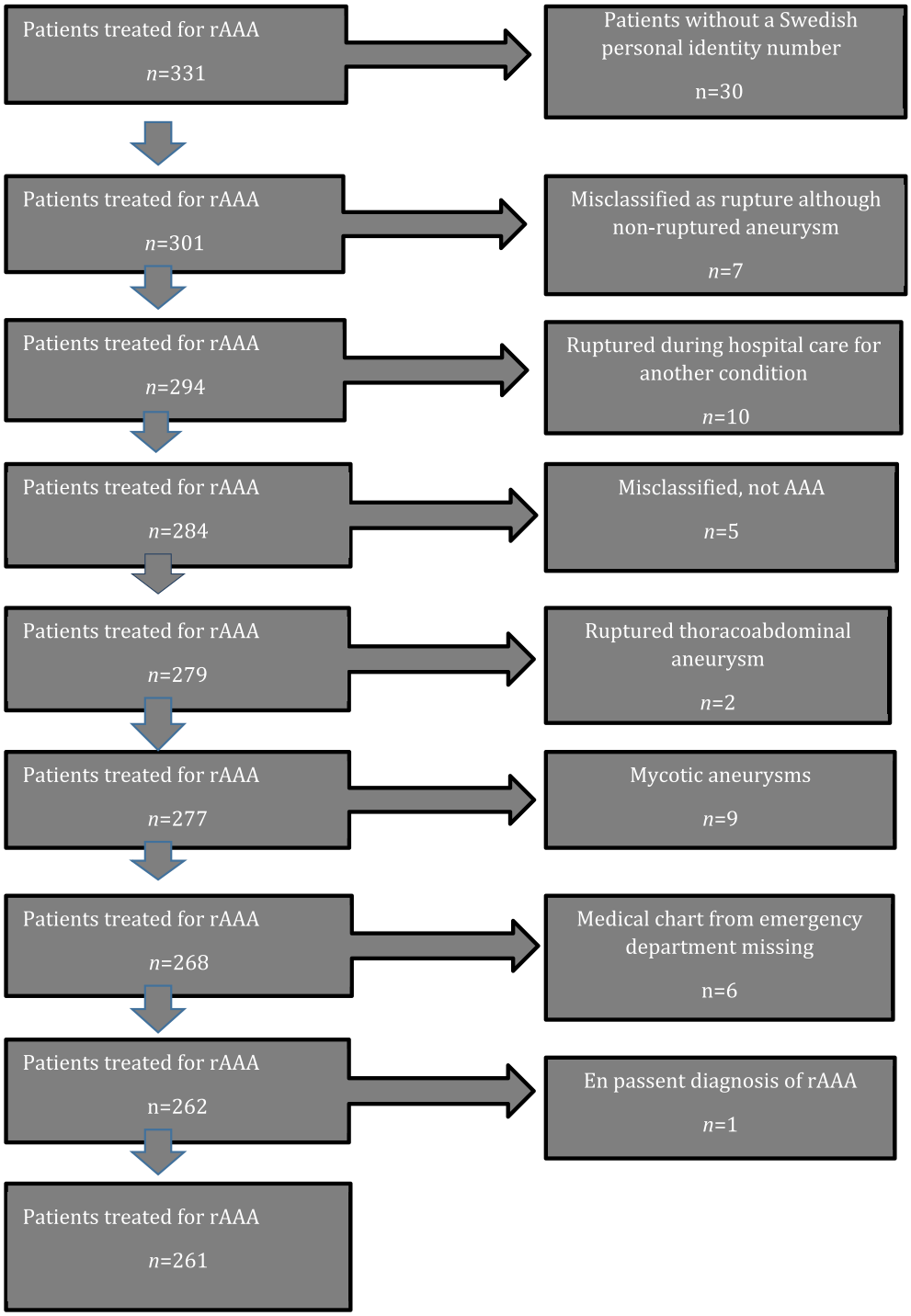

Figure 1. Flowchart of patient selection. *Note.* rAAA = ruptured abdominal aortic aneurysm.

The seven patients excluded owing to misclassification in the registry are described in Table S1 (see Supplementary Material). The ten patients with rupture of an abdominal aortic aneurysm during treatment in hospital for another condition are described in Table S2 (see Supplementary Material), and they were also excluded from analysis.

Of the 261 patients, 187 (71.6%) were primarily assessed by a surgeon or urologist; 53 (20.3%) by an internist, 12 (4.6%) by an emergency medicine physician; and three (1.1%) by an orthopaedic surgeon. Data regarding which clinic was responsible for the first assessment was missing in five (1.9%) patients. In all, 201 (77.0%) patients were treated by OSR and 60 (23.0%) by EVAR. The proportion of EVAR performed annually increased from 20% to 50% during the study period. Some 106 (40.6%) patients were pre-operatively transferred from a primary hospital to one of the four vascular centres within the region. There was no significant difference in 30 day mortality between transferred patients and patients treated at the first hospital they arrived at (24 [22.6%] vs. 49 [31.6%]; $p = .12$).

Baseline data

There were no differences in pre-operative comorbidities (cardiac disease, pulmonary disease, hypertension, previous transient ischaemic attack/stroke, and renal failure defined as pre-operative creatinine > 150 µmol/L) between patients in the correct diagnosis versus those in the misdiagnosis group. The mean age in the correct diagnosis group was 1 year older than in the misdiagnosis group, but this difference was not significant. There was a significantly higher proportion of patients with a first BP ≤ 90 mmHg in the correct diagnosis group. Baseline data are shown in Table 1.

Misdiagnosis rate

In total, 86 (33.0%; 95% confidence interval [CI] 27.2—38.7%) of the patients were misdiagnosed at the primary assessment in the ED. There was a trend towards more frequent misdiagnosis in women versus men (26 [43.3%] vs. 60 [29.9%]; $p = .061$). Patients with a first recorded systolic BP (SBP) < 90 mmHg were less frequently misdiagnosed than patients with a first recorded BP > 90 mmHg (11 [14.7%] vs. 75 [40.8%]; $p < .001$). Patients primarily assessed by an internist were more frequently misdiagnosed compared with patients primarily assessed by a surgeon (30 [56.6%] vs. 48 [25.7%]; $p < .001$).

Time

Some 220 (84.3%) of the patients were transported by ambulance, while 41 (15.7%) patients arrived in the ED as walk-ins. The median time from the patient reported onset ($n = 166$) of symptoms to calling for an ambulance was 3.0 hours (interquartile range [IQR] 0.6—7.3). The median time from the onset of symptoms to arrival at the first hospital (including patients not transported in ambulance) was 4.6 hours (IQR 1.9—9.8) ($n = 192$). The median time from arrival in the first hospital to start of the procedure was 2.1 hours (IQR 1.4—5.7) for patients who received surgical intervention at the first hospital they arrived at and 4.5 hours (IQR 2.8—7.8) for patients transferred from the first hospital to a vascular centre. The overall median time from arrival in the first hospital to start of procedure (OSR or EVAR) was 3.3 hours (IQR 1.8—7.1) ($n = 241$). The median time from arrival at the first hospital to start of procedure was 2.2 hours (IQR 1.3—3.5) for hypotensive patients with a first recorded BP ≤ 90 mmHg versus 4.1 hours (IQR 2.1—9.4) for patients with a first recorded BP > 90 mmHg ($p < .001$).

The median time from arrival at the first hospital to start of the procedure was 7.3 hours (IQR 4.0—18.5) for primarily misdiagnosed patients versus 2.5 hours (IQR 1.6—4.2) for primarily correctly diagnosed patients ($p < .001$).

Mortality and treatment aspects

The overall mortality at 30 days was 28% (73/261 patients [95% CI 22.5—33.4%]). There was no difference between the two groups in terms of 30 day mortality (27.9% vs. 28.0%), 90 day mortality, need for haemodialysis support, time on a ventilator, ICU stay, or duration of hospitalisation (see Table 2).

The 30 day mortality was significantly higher in women compared with men (40.0% vs. 24.4%; $p = .022$). A lower mortality was also observed in patients primarily assessed by a surgeon than in patients primarily assessed by an internist (25.1% vs. 41.5%; $p = .025$). Patients with a first recorded SBP ≤ 90 mmHg did not have a higher 30 day mortality than patients with a first recorded SBP > 90 mmHg (29.3% vs. 27.7%; $p = .88$). Mortality at 30 days was 31.6% in patients treated at the first hospital they arrived at and 22.6% in patients transported to a secondary hospital ($p = .12$).

The odds ratio (OR) for mortality within 30 days analysed by univariate regression analysis followed by multivariate analysis is shown in Table 3. The adjusted OR for mortality within 30 days was 0.78 (95% CI 0.38—1.60) in patients primarily misdiagnosed compared with patients who were primarily correctly diagnosed with rAAA. Female sex remained a risk factor for 30 day mortality (OR 2.32, 95% CI 1.15—4.67) in the adjusted analysis.

Table 1. Clinical characteristics and risk factors in patients with ruptured abdominal aortic aneurysm correctly diagnosed versus misdiagnosed at the first assessment in the emergency department.

Clinical characteristics	Correct diagnosis	Misdiagnosis	*p*
Female	19.4	30.2	.061
Mean ± SD age (y)	75 ± 7.7	74 ± 7.4	.166
Open repair	77.1	76.7	1.00
Cardiac disease	40.8	40.0	1.00
Pulmonary disease	20.0	26.9	.246
Previous TIA/stroke	11.5	14.5	.530
Hypertension	72.7	70.4	.748
Pre-operative creatinine >150 µmol/L	20.0	15.1	.396
First SBP ≤ 90 mmHg	37.0	12.8	<.001

Note. Data are % unless otherwise indicated. SBP = systolic blood pressure; TIA = transient ischaemic attack.

Table 2. Mortality, need for post-operative haemodialysis, days on ventilator, days in the intensive care unit (ICU), length of hospital stay, and proportion of patients able to return to their own home at discharge.

	Correct diagnosis n (%)	Misdiagnosis n (%)	p value
30-d mortality	49 (28.0)	24 (27.9)	1.00
90-d mortality	57 (32.6)	32 (37.2)	.49
Need for post-operative haemodialysis	35 (22.0)	16 (20.5)	.87
Median (IQR) days on ventilator	1 (1—5)	1.5 (0—6)	.90
Median (IQR) days in ICU	4 (2—11)	3.5 (2—9)	.73
Median (IQR) length of hospital stay	14 (6—32)	14 (8—23.5)	.77
Discharged to own home	99 (56.6)	48 (55.8)	1.0

Note. Data are *n* (%) unless otherwise indicated. IQR = interquartile range.

DISCUSSION

Around one third of patients with rAAA are initially misdiagnosed. Given the acute nature of the disease, there is reason to believe that the time delay caused by initial misdiagnosis could worsen the prognosis. This study used data from 261 patients treated for rAAA to test the hypothesis that mortality and complications are more frequent in patients treated for rAAA if they were initially misdiagnosed. The data did not support this hypothesis. The initial misdiagnosis caused an almost 5 hour (median value) delay to surgical treatment, but despite this the 30 day mortality was similar in patients who were initially misdiagnosed compared with patients who were correctly diagnosed (27.9% vs. 28.0%). Confounding factors might influence the result, but a binary logistic regression model adjusted for significant risk factors failed to demonstrate that initial misdiagnosis had any influence on mortality among patients treated for rAAA. Furthermore, no difference in need for post-operative ventilator support, haemodialysis, intensive care, and length of hospital stay between the two cohorts was observed. The initial blood pressure registrations indicate that the misdiagnosis group was haemodynamically more stable and thus tolerated a delay to intervention without impact on outcome.

The proportion of patients who were initially misdiagnosed (33%) was slightly higher in this study than in a recent study by Metcalfe *et al*. (25.6%),[21] but similar to the 32% reported in a review and meta-analysis by Azhar *et al*.[13] Mortality comparisons in misdiagnosed patients versus correctly diagnosed patients are scarce in the literature. Marston *et al*. also failed to demonstrate any difference in mortality,[12] and to the best of the current authors' knowledge, no previous study has reported mortality adjusted for confounders in this setting, which is important as there is reason to believe that selection bias may influence the result.

An observation in this study was a trend towards more frequent misdiagnosis in women versus men (43.3% vs. 29.9%; $p = .061$) and also an associated higher 30 day mortality in women (40.0% vs. 24.4%; $p = .022$). Hence, when adjusted for other risk factors, the 30 day mortality risk was more than doubled in women compared with men (OR 2.32, 95% CI 1.15−4.67). The data lend further support to previous reports of higher mortality in women with rAAA.[26,27] However, the primary aim of this study was not to evaluate the sex perspective.

The study showed a significantly higher frequency of misdiagnosis in patients primarily assessed by an internist compared with patients primarily assessed by a surgeon. The crude OR for mortality at 30 days was 2.11 (95% CI 1.12−4.00) for patients primarily assessed by an internist compared with a surgeon. However, in the adjusted model, only a non-significant trend towards a higher mortality in patients primarily assessed by an internist was observed. Presumably, this difference is explained by a selection bias. This is supported by the fact that 69.8% of patients primarily assessed by an internist had syncope as part of their presenting symptoms compared with only 38.5% of patients primarily assessed by a surgeon ($p < .001$). Nonetheless, a misdiagnosis rate of 56.6% suggests that a higher awareness of the diagnosis is needed among internists, which is also supported by Lederle *et al*.[19]

A strength of this study is the large number of patients and events, allowing for analysis of confounders related to mortality and complications.

The patients in this study were identified through the Swedvasc registry. Swedvasc contains data regarding patients who have undergone a vascular procedure. Thus, patients with rAAA who have not undergone operative treatment are not included in the study, and this is recognised as a limitation. There is reason to believe that there might be patients

Table 3. 30 day mortality in patients with ruptured abdominal aortic aneurysms.

	OR crude mortality at 30 d	95% CI	p[a]	OR adjusted mortality at 30 d[b]	95% CI
Misdiagnosis	1.0	0.56−1.77	.99	0.78	0.38−1.60
Age (per year) (missing = 0)	1.05	1.01−1.09	.02	1.05	1.00−1.10
Females (missing = 0)	2.07	1.13−3.80	.02	2.32	1.15−4.67
OSR (compared with EVAR) (missing = 0)	1.99	0.97−4.08	.06	1.76	0.75−4.15
Transportation to secondary hospital (missing = 0)	0.63	0.36−1.12	.11	0.59	0.30−1.18
Respiratory disease (missing = 28)	2.11	1.10−4.04	.02	1.95	0.95−4.02
First assessment by internist (compared with surgeon) (missing = 21)	2.11	1.12−4.00	.02	2.01	0.94−4.28
Previous heart condition (missing = 24)	1.61	0.90−2.90	.11		
Previous TIA/stroke (missing = 28)	0.88	0.36−2.19	.79		
Creatinine >150 µmol/L (missing = 8)	1.44	0.73−2.84	.29		
Hypertension (missing = 51)	1.95	0.91−4.20	.09		
First- recorded BP ≤ 90 mmHg (compared with > 90 mmHg) (missing = 2)	1.08	0.60−1.96	.79		
Reported syncope (missing = 0)	0.91	0.53−1.58	.75		

Note. OR = odds ratio; CI = confidence interval; OSR = open surgical repair; EVAR = endovascular aortic repair; TIA = transient ischaemic attack; BP = blood pressure. [a] p values for the univariate analysis. [b] Multivariate logistic regression analysis adjusted for misdiagnosis/correct diagnosis, age, sex, open repair/EVAR, primary assessment by internist/surgeon, respiratory disease and transportation to secondary hospital.

who were misdiagnosed and who were therefore sent home from the ED or were admitted to a ward and died without receiving surgery. Further research is warranted to try to identify such cases. Nevertheless, the study provides important information about the frequency of misdiagnosis, time lost in misdiagnosed patients, and the clinical consequences of misdiagnosis in patients treated for rAAA.

A further limitation is the observational character of the study and the risk of bias associated with this study design. There might be a remaining unmeasured selection of cases and unknown confounders might exist, but an extensive analysis of potential confounders has been made and it is believed that remaining confounding is probably limited. Coding errors and misclassifications are possible, but, if present, it is believed to be non-differential.

In conclusion, misdiagnosis is common in patients with rAAA, and treatment is significantly delayed in misdiagnosed patients. The study did not show any survival disadvantage or increased frequency of post-operative complications in misdiagnosed patients despite the delayed treatment. However, only patients who reached surgical intervention were included in the analyses.

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CONFLICTS OF INTEREST

None.

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APPENDIX A. SUPPLEMENTARY DATA

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.ejvs.2017.03.022.

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COUP D'OEIL

A Retrograde Endo-bypass to Revascularise an Isolated Internal Iliac Artery

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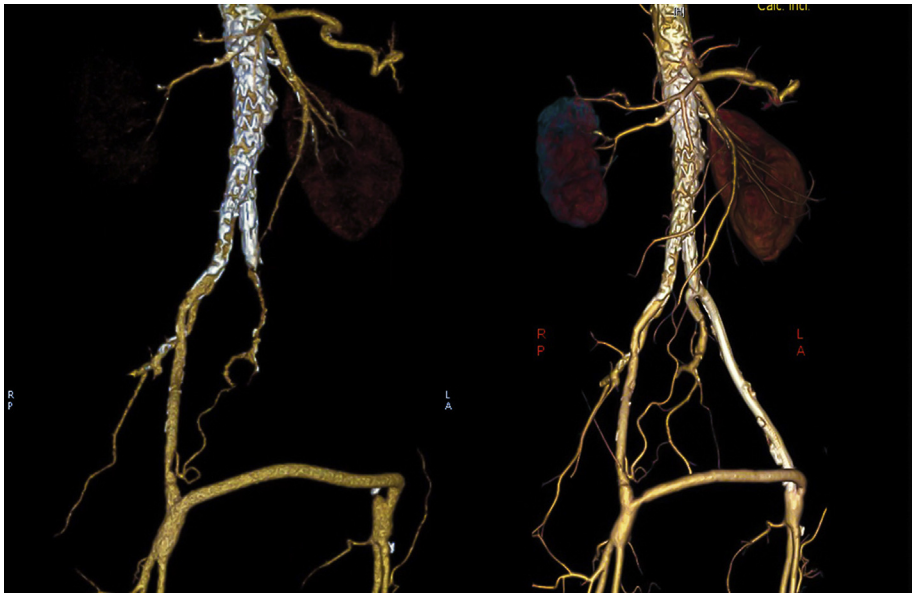

An 83 year old man presented with severe left buttock claudication 2 months after treatment of an abdominal aortic atherosclerotic ulcer with an aorto-uni-iliac endoprosthesis, a left common iliac occluder and a right to left femoro-femoral crossover bypass. Computed tomography angiography showed an occluded left external iliac artery (LEIA) with an underfilled left internal iliac artery (LIIA). Via open femoral access, subintimal recanalisation of the LEIA was performed, followed by placement of two 7 × 150 mm VIABAHN® endoprostheses (WL Gore & Associates, Flagstaff, AZ, USA), resulting in successful retrograde inflow to the LIIA and complete recovery of the patient's symptoms.

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