Eur J Vasc Endovasc Surg (2017) ■, 1–7

Trends in Patient Safety of Intact Abdominal Aortic Aneurysm Repair: German Registry Data on 36,594 Procedures

M. Trenner [a], B. Haller [b], M. Storck [c,d], B. Reutersberg [a], M.A. Kallmayer [a], H.-H. Eckstein [a,*]

[a] Department of Vascular and Endovascular Surgery, Klinikum rechts der Isar, Technical University of Munich, Munich, Germany
[b] Institute for Medical Statistics and Epidemiology, Technical University of Munich, Munich, Germany
[c] Department for Vascular and Thoracic Surgery, Städtisches Klinikum Karlsruhe, Karlsruhe, Germany
[d] Commission for Quality and Safety, German Vascular Society (Deutsche Gesellschaft für Gefäßchirurgie und Gefäßmedizin, DGG), Berlin, Germany

WHAT THIS PAPER ADDS

Temporal trends for a 12 year period in elective abdominal aortic aneurysm surgery show reduction of complication rates resulting in decreased mortality, while the treated patient's age and American Society of Anesthesiologists scores increased. In the same time period endovascular repair was implemented as the standard of care. In hospital patient safety improved significantly. Trends in complication rates and mortality have not been shown before for such a long time period and large cohort.

Objective/Background: The study aim was to determine whether patient safety for non-ruptured abdominal aortic aneurysm (nrAAA) repair has changed between 1999 and 2010 in a large German cohort.

Methods: The data source was the prospective quality assurance registry of the German Vascular Society from 1999 to 2010. Patient characteristics, surgical techniques (open aortic repair [OAR], endovascular aortic repair [EVAR]), procedural time and outcomes, including the length of hospital stay (LOS), were analysed using the Cochran–Armitage test for binary parameters and Spearman's correlation coefficient for quantitative parameters.

Results: A total of 36,594 operations (23,037 OAR, 13,557 EVAR) for infrarenal nrAAA in 201 hospitals in Germany were investigated. Patients' mean age increased from 69.6 to 72.0 years ($p < .001$). The rate of patients with American Society of Anesthesiologists scores of 3 or 4 increased ($p < .001$). Use of EVAR increased (1999: 16.7%; 2010: 62.7%; $p < .001$), and since 2009, EVAR has been more frequently used than OAR. The overall in hospital mortality decreased from 3.1% in 1999 to 2.3% in 2010 ($p < .001$). There were no temporal trends for mortality rates for EVAR ($p = .233$) or OAR ($p = .281$) when considered separately. Cardiac (1999: 8.1%; 2010: 5.1%; $p < .001$) and pulmonary (1999: 7.8%; 2010: 4.8%; $p < .001$) complications decreased. The rate of post-operative renal failure increased (1999: 3.6%; 2010 4.1%; $p = .017$), without increasing the rate of patients needing dialysis (1999: 1.7%; 2010: 1.7%; $p = .171$). The median LOS decreased from 17 days in 1999 to 10 days in 2010 ($p < .001$).

Conclusion: This study shows significantly improved post-procedural in hospital outcomes and decreased use of resources for nrAAA repair. This trend can probably be attributed to the implementation of EVAR as a standard technique, but some trends could also possibly be explained by a change in the remuneration system. The main limitation of the registry is the lack of internal and external validation. However, in hospital patient safety for AAA repair seems to have improved significantly in the participating hospitals.

Article history: Received 26 September 2016, Accepted 14 December 2016, Available online XXX

Keywords: Abdominal aortic aneurysm, Endovascular aortic repair, Open aortic repair, Patient safety, Quality assurance

INTRODUCTION

To justify any interventional procedure for abdominal aortic aneurysm (AAA), it has to be as safe as possible. Elective open aortic repair (OAR) can be associated with severe complications, especially in elderly and multi-morbid patients. With the implementation of endovascular aortic repair (EVAR), fewer procedural complications and fatalities are to be expected.

* Corresponding author. Department for Vascular and Endovascular Surgery, Klinikum rechts der Isar der Technischen Universität München, Ismaninger Str. 22, 81675 München, Germany.

E-mail addresses: hans-henning.eckstein@mri.tum.de (H.-H. Eckstein).

1078-5884/

http://dx.doi.org/10.1016/j.ejvs.2016.12.024

Please cite this article in press as: Trenner M, et al., Trends in Patient Safety of Intact Abdominal Aortic Aneurysm Repair: German Registry Data on 36,594 Procedures, European Journal of Vascular and Endovascular Surgery (2017), http://dx.doi.org/10.1016/j.ejvs.2016.12.024

EVAR was introduced as a standard procedure in Germany in the early 2000s. In order to describe changes in AAA treatment in the endovascular era, this study aims to report temporal trends regarding patient characteristics, surgical techniques and outcomes (mortality, morbidity) over a 12 year time span (1999–2010) in patients who received treatment for non-ruptured (nr)AAA.

METHODS

The rationale of the prospective quality assurance registry on AAA of the Deutsche Gesellschaft für Gefäßchirurgie (DGG) was to give the participating centres annual benchmark reports about their individual results in AAA care. While participation is mandatory for certified vascular centres, all other departments participate voluntarily. The registry was launched in 1997 and it obtained detailed information on the state of AAA care, including information about patient characteristics, AAA morphology, surgical techniques, and peri-operative outcomes. The registry also enables participants to benchmark their own data with those of other participating hospitals. Although the recording of all relevant pre-, intra-, and post-operative data was initially performed using machine readable forms, online data registration has been used in more recent years. Once a year, data of the individual hospitals and of the entire registry are made available to the participants. Hospitals are self responsible for data validity.

Registry data have been analysed and published recently. The first publication mainly focused on a comparison between EVAR and OAR.[1] The second publication was an analysis of peri-operative predictors for mortality and the relationship between hospital volume and outcome.[2]

Patients

Data of the prospective AAA quality assurance registry of the DGG from 1 January 1999 to 31 December 2010 were analysed. The participating hospitals provided data for patients receiving treatment for intact and ruptured infra- and juxtarenal AAA (International Classification of Diseases-10 I71.3, I71.4). Overall, 201 hospitals participated in the registry, with a mean of 104 hospitals/year. Patients with ruptured AAA were excluded from this study. Individual patient characteristics (age, American Society of Anesthesiologists [ASA] score, AAA diameter), surgical techniques (OAR, EVAR, procedural time), and outcomes (peri-operative mortality and morbidity/complications, length of hospital stay [LOS]) were analysed. The participating hospitals were responsible for consenting the patients for anonymous data collection and analysis.

Primary outcome

The primary outcome of this study was in hospital mortality. Secondary outcome parameters were post-operative complications (cardiac, pulmonary and renal complications, dialysis, sepsis, wound infection, bleeding, peripheral ischaemia, and visceral ischaemia). The occurrence or absence of post-procedural complications during the hospital stay was assessed by the treating physician according to general clinical standards. Studied complications included cardiac complications (myocardial infarction and post-operative cardiac insufficiency), pulmonary complications (long-term ventilation, pneumonia, pulmonary insufficiency, pulmonary embolism), renal complications (new incidence of renal insufficiency, renal embolism), need for dialysis, sepsis, wound infections, bleeding with need for re-intervention, peripheral ischaemia, and visceral ischaemia. Endoleaks were not included in the outcome analysis because they are specific to EVAR.

Statistical analysis

Continuous data are represented by mean and SD or median. For categorical variables, absolute and relative frequencies are shown. Temporal trends were analysed statistically using the Cochran–Armitage test for binary and Spearman's correlation coefficient for quantitative outcomes. Extreme outliers ($<$2.5 cm; $>$20 cm) in AAA diameter were considered as input errors and excluded from the description of mean AAA diameter. Single missing values were excluded from analysis. Statistical analyses were performed using the software R version 2.15.1 (R Foundation for Statistical Computing, Vienna, Austria) and SPSS version 20.0 (IBM, Armonk, NY, USA). For all tests, a two-tailed level of significance of $\alpha = 5\%$ was used.

RESULTS

Patient characteristics

In total, 36,594 operative procedures for nrAAA were available for analysis (23,037 OAR, 13,557 EVAR). The mean age of the patients was 71 $\pm$ 8.0 years. Mean age increased from 69.6 $\pm$ 7.6 years in 1999 to 72.0 $\pm$ 8.3 years in 2010. A total of 66.7% of patients were classified as having ASA scores of 3 or 4. The rate of patients who scored ASA 3 and 4 increased, and those scored ASA 1 and 2 significantly decreased. The median AAA diameter was 55 mm (interquartile range 50–65 mm). The rate of iliac aneurysm extent, including concomitant iliac artery aneurysms, was 31.2%. Inflammatory AAA aetiology was present in 3.5% of the patients. Temporal trends in patient characteristics are presented in Table 1 for all patients and in Table 4, for comparison of EVAR and OAR.

Procedural parameters

EVAR was used in 37% of the cases. In 1999, only 16.7% of the patients received endovascular treatment, and 2009 was the first year in which over half of the patients received EVAR. A significant trend in the use of endovascular therapy was found (Fig. 1, Table 2). EVAR was performed under local or regional anaesthesia in 11.6%, while 99.6% of patients who had OAR received general anaesthesia. In OAR, suprarenal clamping was necessary in 9.8%, with an increasing trend (Table 2). In total, 294 (4.3%) of the patients were treated with special custom made devices. The overall median procedural time was 145 min. A decrease in median

Please cite this article in press as: Trenner M, et al., Trends in Patient Safety of Intact Abdominal Aortic Aneurysm Repair: German Registry Data on 36,594 Procedures, European Journal of Vascular and Endovascular Surgery (2017), http://dx.doi.org/10.1016/j.ejvs.2016.12.024