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A Gender-Focused Analysis of 36 Perioperative Risk Factors on Long Term Survival of Acute Type A Aortic Dissection - Equal Chances?

Frank Harig[1], Anna Engel[2], Johannes Rösch[1] and Michael Weyand[1]*

[1]*Department of Cardiac Surgery, University Hospital Erlangen, Germany*

[2]*Department of Cardiology and Angiology, University Hospital Erlangen, Germany*

Abstract

We focused on gender specific perioperative risk factors for the survival of an acute Stanford type A aortic dissection.

A cohort of 147 patients undergoing surgery since 2004 was studied in a 9 year follow-up. Analysis was performed using Cox-proportional hazard model focusing on 36 variables.

Survival after 1 y (5y, 10y) was 98% (88%, 50%). Early mortality was 25%, 27% female, with a higher age (+10 y, mean, 64 ± 10 y) than men. In the 7th decade, percentage of women was as twofold higher and threefold higher in the 8th decade. Survival probability (Log rank test) for the first postoperative year was 0.82/0.77 (female/male) for 5 years 0.70/0.71, and 0.46/0.50 for 10 years. Risk factor analysis showed women having a high hazard ratio for death in case of re-sternotomy (16.543), bleeding (8.1), and renal insufficiency (3.4).

Only EURO-Score (1.103, p=0.038) and length of hospital stay (0.849, p=0.015) were significant risk factors for death.

The survival curve declines between 5 and 10 years (88% to 50%). In male patients, age and resternotomy had a significant influence on survival. Women had a higher incidence for aortic type a dissection in the 7th and 8th decades. Gender did not influence survival.

Keywords: Aortic type A dissection; Gender specific risk factors; IRAD

Correspondence:
Frank Harig, Department of Cardiac Surgery, University Hospital Erlangen, Friedrich-Alexander University Erlangen-Nuremberg, Krankenhausstr, 12 D-91054 Erlangen, Germany, Tel: 0049-9131-853.7066; Fax: 0049-9131-853.7058;
E-mail: frank.harig@uk-erlangen.de

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Introduction

Although the surgical treatment of dissections was established more than 6 decades ago [1] and a lot of techniques have been established (Wheat [2], Bentall [3], David [4]) this acute disease and life-threatening clinical event still bears a high mortality of 1% to 2% per hour within the first days [5,6].

Among several studies, the analysis of the International Registry of Acute Aortic Dissection (IRAD-trial [7]), is the most detailed analysis of patients with aortic dissections (type A and B). Within this registry, patients with type A dissection revealed an overall mortality of 30%, the surgical type A treatment showed 25% and the medical treatment of type A dissection showed a 56% in hospital mortality [7,8].

There are still a lot of questions to be answered in order to achieve an optimal treatment. One of those questions is the difference between the genders and, for example, the delay in finding the correct diagnosis. As already known from acute coronary syndromes, women are treated with a delay in diagnosis, may be due to different pain perception or less typical pain [9-11].

As the time interval needed for the correct diagnosis is still too large (in the IRAD trial [7], 56 hrs from symptom onset to diagnosis for women and 50 hrs for men) efforts have to be made to get the correct diagnosis in a shorter time period. In the IRAD-trial, a diagnosis could be found in 40% of women and in 30% of men beyond a time period of 24 hrs. These finding suggest that there are still efforts to be made for earlier recognition (diagnostic findings) and optimal medical treatment.

In the definite treatment of Stanford type A dissections some questions arise considering the treatment strategy of women because there are data indicating that women were less frequently

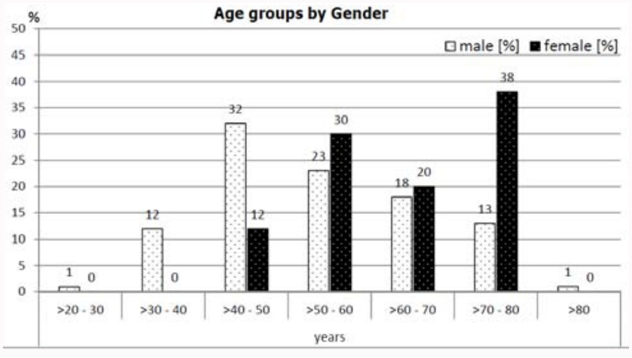

Figure 1: Age groups by gender.
Legend: Values are (%)

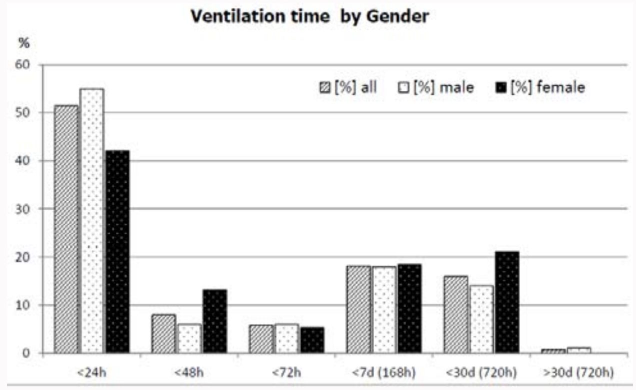

Figure 2: Ventilation time by gender.

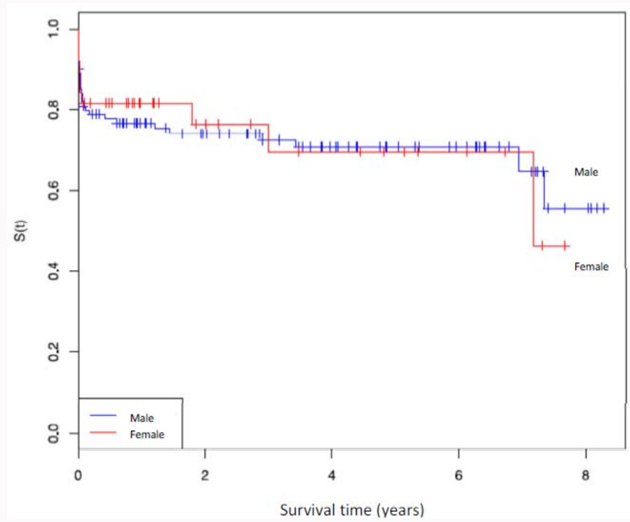

Figure 3: Kaplan-Meier- estimation for survival stratified for gender.
Legend: Cumulative Survival S (t) over the time; blue line: men; red line: women

surgically treated than men (in a large trial of the year 2004 (IRAD [7]), 70% female *vs.* 86% male patients). A conservative medical treatment in women was chosen in 28%, whereas men were medically treated only in 13%. However, the outcome of women treated medically in type A dissection is nearly as bad as in men (53% let. *vs.* 58% in men). This is the reason why operative treatment in type A dissection is the method of choice.

Another one is the difference in outcome between the genders. Highest mortality is seen in female patients with type A dissection submitted to surgery (IRAD [7]: 32 *vs.* 22% (female *vs.* male)).

This raises the question if the medical treatment process from diagnostic to surgical intervention bears some potential of optimization in the future.

It remains unclear why women have to face a higher mortality in surgically treated type A dissection (32%) than men (22%). The question arises if women are put at a disadvantage secretly, may be because of older age or bad medical status.

On the other hand, data from well performed trials have to be transformed into actual decades and need to be modified by current surgical techniques (like selective antegrade cerebral perfusion and mild hypothermia) and knowledge (e.g. in the IRAD-trial, data collection began in 1996).

Aim of this study was the evaluation of 36 perioperative risk factors influencing the survival of patients with an acute type A aortic dissection with a special focus on gender specific risk factors. In the future, management of this disease and outcome in both genders but especially in women may be improved.

Materials and Methods

We studied a 9-year follow-up of a cohort of 147 patients with the diagnosis of acute type A dissection undergoing emergency surgery in our institution from 2004 to 2014. Follow-up was performed by contacting the patient and the primary care physician/practitioner to get information about the patients' clinical status. Follow-up completeness was 99.1%. Aim of the study was the evaluation of pre-, intra- and post-operative risk factors and their influence on survival after aortic repair for aortic dissection. One focus was the question if there were gender specific risk factors.

Statistical analysis

Statistical analysis was performed using Cox-proportional hazard model focusing on 36 variables. Processing of data was done by a statistician using software package R (R-Foundation for statistical computing, Vienna, Austria) [12]. In order to detect the variables with the highest impact on survival and their effect on the hazard rate, a two-step procedure was applied. In a first step, the statistical method called "boosting" was applied in order to select a subset of variables with highest impact for survival [13,14]. "Boosting" is a method for the selection of variables in the case of dealing with a high number of potential risk factors. In a second step, a Cox- Proportional Hazards model was processed using the selected risk factors in further detail [15]. This analysis was applied in the cohort of female and male patients in order to detect possible differences. The definition of "hazard rate":

The Hazard rate λ (t) is defined as the risk to die in the next moment if having survived until now. The definition of "hazard ratio (HR)": HR is a ratio of hazard rates, i.e. patients with and without a risk factor:

HR= λ(t) with risk factor/λ(t) without risk factor

Results

Early mortality (30 d) was 25% (n=37), 27% of patients were female, with a higher age (+10 y, mean, 64 y ± 10 y) compared to men. In the 8th decade, percentage of women was threefold higher as in men (38% *vs.* 14%), whereas the 5th decade was dominated by a

Table 1: Demographics and clinical data of patients by gender.

	overall	male	female	*P*
Demographic data				
n [%]	**147** (100%)	107 (73%)	40 (27%)	…
age [years],	56.4 (12.8)	53.4 (12.6)	64.4 (9.5)	0.003
Body mass index [BMI]	28.9 (5.7)	29.8 (5.9)	26.8 (4.6)	0.001
History of hypertension	87 (63.0%)	60 (60%)	27 (71.0%)	n.s.
Antihypertensive medication	77 (55.8%)	51 (51%)	26 (68.4%)	0.099
Diabetes mellitus	5 (3.6%)	3 (3%)	2 (5.3%)	n.s.
Preop. clinical signs and presentations				
myocardial infarction	6 (4.4%)	4 (4%)	2 (5.3%)	n.s.
Resuscitation	4 (2.9%)	4 (4%)	0	n.s.
Cardiogenic shock/ catecholamines	13 (9.4%)	10 (10%)	3 (7.9%)	n.s.
Creatinine at admission	1.2 (0.54)	1.3 (0.56)	0.99 (0.44)	n.s.
EuroSCORE (logistic)	31.4 (17.7)	28.6 (15.6)	38.6 (29.8)	0.03
Previous cardiac surgery	7 (5%)	6 (6%)	1 (2.6%)	n.s.
Aortic valve compromise	64 (46.4%)	49 (49%)	15 (39.5%)	n.s.
Carotid arteries compromise	34 (25%)	24 (24%)	10 (26%)	n.s.
LV-function, EF >50%	83 (91%)	59 (92%)	24 (89%)	n.s.
Any focal neurological deficit	29 (20%)	20 (21%)	8 (20%)	n.s.
Clinical and surgical data				
OP-time	331 (112)	335 (116)	322 (102)	n.s.
Time on pump/ ECC-time	181 (81)	180 (83)	181 (78)	n.s.
Cross-clamp time	99.4 (48)	99.9 (49)	97.8 (47)	n.s.
Intra-OP transfusion	134 (97%)	97 (97%)	37 (97%)	n.s.
Cardiocirculatory assist (IABP, ECMO)	10 (8%)	6 (6%)	4 (11%)	n.s.
Weaning from respirator	217 (487)	237 (556)	164 (221)	n.s.
ICU- stay	7.1 (11.2)	7.4 (12.4)	6.3 (6.9)	n.s.
Hospital stay	16.1 (13.3)	16.2 (14)	16 (11.3)	n.s.
Complications and mortality				
Bleeding*	36 (26.1%)	24 (24%)	12 (32%)	n.s.
Reexploration: bleeding/ tamponade**	23 (16.7%)	16 (16%)	7 (18%)	n.s.
Pneumonia	39 (28.3%)	30 (30%)	9 (24%)	0.06
Wound dehiscence/ infection	5 (3.6%)	5 (5%)	0	n.s.
Neurological deficits	37 (27%)	28 (28%)	9 (24%)	n.s.
Hemiparesis	13 (9%)	8 (8%)	5 (13%)	n.s.
Intracerebral bleeding	3 (2.2%)	2 (2%)	1 (2.6%)	n.s.
Creatinin at admission	1.2 (0.54)	1.3 (0.56)	0.99 (0.44)	n.s.
Creatinin max [mg/dl]	2.1 (1.55)	2.4 (1.67)	1.64 (1.02)	n.s.
Creatinin at discharge	1.3 (1.11)	1.4 (1.23)	1.02 (0.58)	n.s.
Dialysis/Hemofiltration	35 (25%)	25 (25%)	10 (26.3%)	n.s.
Mortality - in hospital (2005-2014)	39 (26.5%)	29 (27.1%)	10/40 (25%)	n.s.
in hospital (2011-2014)	7/47 (14.9%)	5/47 (10.6%)	2/47 (4.3%)	n.s.
Operative mortality	9/147 (6.1%)	7/107(6.5%)	2/40 (5%)	n.s.

Legend: Values are n (%) or mean + SD; *p<0.05, n.s.: Not Significant; Euro SCORE: European System for Cardiac Operative Risk Evaluation [16]; ECC: Extracorporeal Circulation; IABP: Intraaortic Balloon Counterpulsation; ECMO: Extracorporeal Membrane Oxygenation; ICU: Intensive Care Unit
*Bleeding was defined as drainage volume over 500 mL and below 1000 mL, which did not require; reexploration (trigger was 200 mL per hour, or 1000 mL in sum)
**Reexploration was done if drainage volume was >1000 mL with normal coagulation lab values

threefold higher incidence of men (32% *vs.* 11% women).

Arterial hypertension was present in 71% of women (69% treated), and 60% in men (50% treated). Preoperative neurological deficits were present in 18% of all. The spectrum of surgical procedures comprised interpositions (58%), Bentall's procedure (39%), and valve sparing procedures (Yacoub's/David's procedures) in 3%. Cannulation site was subclavian and innominate artery (74%), femoral (14%) and aortic arch (10%).

Follow-up was 99%. Survival after 1/5/10 years was 98%/88% and 50%, respectively. Survival probability (Log rank test) for the first postoperative year was 0.82/0.77 (female/male) for 5 years 0.70/0.71, and 0.46/ 0.50 for 10 years (log rank test for gender was not significant, p=0.964). Risk factor analysis showed women having a high hazard ratio for death in case of re-sternotomy (16.543), bleeding (8.1), and renal insufficiency (3.4).

Only EURO-Score (1.103, p=0.038) and length of hospital stay (0.849, p=0.015) were significant risk factors for death. Male patients had a high hazard ratio for re-sternotomy (6.7), apoplexy (2.1), renal insufficiency (1.5), only re-sternotomy (6.7) and age (1.05) reached level of significance.

Demographic factors

Age and gender proportion in different age groups: We could observe gender-related differences in demographics. Of 147 patients with acute Stanford Type A dissection, 27% were female, and 73% were male. Women (64 y ± 10 y) were 10 years older than men (53.4 y ± 12 y) (P=0.03). Consequently, in the 8^{th} decade, percentage of women was threefold higher as in men (38% *vs.* 13% men) whereas in the 5^{th} decade, percentage of men was threefold higher as in women (32% *vs.* 12%) (Figure 1).

A higher age was a risk factor for survival in men (10% more risk of mortality for 10 more years of age).

Hypertension and body mass index: Arterial hypertension was present in nearly two thirds (63%) of all patients (71% of women, and 60% in men. More women suffered from arterial hypertension, and women had a stronger adherence to medication than men.

Treatment with antihypertensive medication was found only in 56% of all (of the latter, 68% women and 51% men).

As one risk factor for hypertension, the body mass index was found significantly higher in men (29.8 ± 5.9) than in women (26.8 ± 4.6, P=0.001) (Table 1).

Preoperative clinical signs and presentations of patients by gender

Preoperative neurological focal deficits occurred without a gender emphasis in 20% of all patients. Hemiparesis was the most common clinical sign (18% in both genders) (Table 1).

The preoperative cardiocirculatory condition was very severe (resuscitation, cardiogenic shock, myocardial infarction) in about 23% of patients (this differs to previous studies (IRAD), where one third of patients were classified as 'high-risk').

In-hospital treatments and surgical data by gender

We could not find differences between the genders concerning the spectrum of surgical procedures that comprised interpositions (58%), Bentall's procedure (39%), and valve sparing procedures (Yacoub/ David) in 3%. The cannulation site was subclavian and innominate artery (74%), femoral (14%) and aortic arch (10%) and was equally contributed between the groups.

However, we did observe that the postoperative occurrence of neurological deficits was higher for femoral cannulations (40.4%) compared to subclavian/axillary cannulations (19.8%, P=0.0168). Femoral cannulation was only used in case of emergent installation of extracorporeal circulation.

The time on pump (ECC-time), cross-clamp time and whole duration of the operation showed no differences (Table 1).

Respiratory function and weaning from the respirator during the ICU stay plays a crucial role. Although women had a shorter all-over weaning time (164 h *vs.* 237 h), and therefore showed a lower incidence of pneumonia (24% *vs.* 30%, P=0.06), (Table 1), the data showed a wide standard deviation and it seemed to be worth analyzing this important postoperative period in detail. Most patients (about 50%, Figure 2) had an intubation time of less than 24 hrs (women 42% and men 55%), within 48 hrs, 55% of women and 61% of men were extubated and breathed spontaneously. Nearly 20% needed nearly one week to get extubated and 22% needed long time intubation, tracheotomy inclusively. A tendency towards longer intubation in women (as can been seen from smaller proportion in the <24 hr group, and a greater part in the <30 d group) was not significant (Figure 2).

Gender specific in-hospital complications and mortality

Bleeding and reexploration: Postoperative bleeding after such severe operations including side effects of a long pump-time occurred in 26% of all patients. Female patients had a higher proportion (32%) as men (24%), without reaching a level of significance and without leading to a higher incidence of reexploration by complete rethoracotomy. The cut off value for reexploration was 1,000 ml of drainage volume under normal global coagulation values after adequate substitution, if necessary. The further risk factor analysis shows a significant higher risk for mortality for men in the case of reexploration for bleeding (hazard ratio 6.7) (Table 2).

Postoperative neurological deficits: We could observe minor and major neurological deficits in 28% of male and 24% of female patients. Major deficits like hemiplegia was most common, in 8% of men and 13% of women (n.s., P=0.767). An intracerebral bleeding was only rarely the cause of major deficits (2% men *vs.* 2.6% women).

Renal insufficiency: A clinical manifestation of a renal insufficiency that may be due to a malperfusion of the kidneys could mostly not be observed ad admission (creatinine, 1.2 mg/dl). At least, the lab parameters (creatinine, BUN) are not as sensible as to indicate a renal problem immediately. A rise of creatinine levels (max. of all, 2.1 mg/dL, male, 2.4; female, 1.6 mg/dL) indicates perfusion variations during the preoperative and intraoperative period (extracorporeal circulation, ECC). Postoperatively, 25% of patients, independent of gender, needed hemofiltration or dialysis, but looking at creatinine levels overall statistically, at discharge they nearly reached preoperative levels (1.3 mg/dL) (Table 1).

Mortality: From 147 patients, 9 patients (6%) died very early, in tabula, among them 7 male (7%, of them 2 cardiogenic and 5 hemorrhagic shocks) and 2 female (5%, 2 cardiogenic shocks). We could observe a total of 39 in house deaths.

27% (n=29) were male and 25% (n=10) female. The most frequent reasons for death were multi-organ failure due to sepsis (28%), cardiac failure (23%) and irreversible brain damage (21%) without any significant emphasis on gender (Table 1).

In our data, mortality dropped from about 25% to 29% (2004-2007) to about 25% (2008-2010) to about 15% (2011-2014). The

Table 2: Risk factor analysis by gender.

	Hazardratio	95%- CI	P-value
women			
Rethoracotomy	16.543	(0.47, 577.41)	0.122
Bleeding	8.184	(0.29, 229.95)	0.217
Creatinine at discharge	3.467	(0.55, 21.67)	0.184
Euro SCORE	1.103	(1.01, 1.21)	**0.038**
OP-Time	1.007	(1, 1.02)	0.175
Hospital stay	0.849	(0.74, 0.97)	**0.015**
Pneumonia	0.062	(0, 1.85)	0.108
men			
Rethoracotomy	6.701	(2.65, 16.94)	**<0.001**
Apoplexia	2.093	(0.74, 5.94)	0.165
Creatinine at admission	1.576	(0.93, 2.67)	0.09
Euro SCORE	1.021	(0.99, 1.06)	0.224
Age	1.05	(1, 1.1)	**0.034**

Legend: Results of the Cox-Modell for selected variables; CI: Confidence Interval; Hazard rate: the risk to die in the next moment, in the case of survival until now; Hazard ratio: The ratio of hazard rates, with and without risk factor

actual data (mortality rate 14% to 15%) comprise 31% of our patients and they are comparable to the international data (12% to 13%).

After reviewing for aortic events in the follow-up, we found 5 possibly aortic events in 5 patients of all survivors (5/138: 3.6%). In this time interval, no aortic redo operations were performed.

Risk factor analysis

Scoring systems like the EURO-Score try to give an objective evaluation of the preoperative clinical status. According to the EURO-Score, women were admitted into hospital in a clinically severely compromised status (ES: 38 *vs.* 28 in men, P=0.03). The risk factor analysis revealed that women have a high hazard ratio for death in case of resternotomy (OR 16.543), bleeding (OR 8.1), and renal insufficiency (OR 3.4). The EURO-Score showed an OR of 1.103, 95% CI, 1.01 to 1.21, P=0.038) and the length of hospital stay as an indicator of survival (OR 0.849, 95% CI, 0.74 to 0.97, P=0.015) were significant (Table 2).

This means that each additional unit of EURO-Score, that reflects the severity of clinical status, leads to a 1.1-fold higher hazard rate, i.e. 10% higher mortality risk. The length of stay shows a reciprocal effect, i.e. every further day leads to a reduction of the hazard rate of 15%. Male patients had a high hazard ratio for resternotomy (OR 6.7), apoplexy (OR 2.1), and renal insufficiency (OR 1.5). Only resternotomy (OR 6.7, 95% CI 2.65 to 16.94, P<0.001) and age (OR 1.05, 95% CI 1.0 to 1.1, P=0.034) reached levels of significance (Table 2). This means, that with each year of age, the hazard rate grows 1.05 -fold, so that a 60 years old patient bears a 10.5-fold higher hazard rate (for mortality) compared to a 50 years old patient (with otherwise identical risk factors) (Table 2).

Survival

The follow-up rate was 99%. Survival declined continuously and after 1, 5, and 10 years it was 98%, 88%, and 50% respectively.

The survival probability (log-rank test) for the first postoperative year was 82% *vs.* 77% (female: male) for 5 years, 70% *vs.* 71%, and 46% *vs.* 50% for 10 years (Figure 3).

Log-rank-Test for cumulative survival could not show a significant gender specific difference (P=0.964).

Discussion

Hypothesis 1: Do women have a higher mortality in CV disease?

In current medical literature, women seem to have a worse outcome in cardiovascular diseases than men, especially in acute coronary syndromes [17]. For example, the German Heart Report showed a higher mortality in women (21% *vs.* 13%) for valvular heart disease in a trend analysis over more than 30 years [18].

In the IRAD-trial [7,8], women had a higher surgical mortality in type A dissection than men (32% *vs.* 22%). Interestingly, in this international trial, women had a higher incidence of type A dissections than men (66% female, 61% male), in our analysis, there were 27% female and 73% male patients. Other investigators [19] published a gender ratio of 1:1.75, female (36%): male (63%), the lower proportion of women is similar to our observations with 25% female patients (gender ratio of 1:2.675). We could not confirm the hypothesis of higher mortality in women. Although women were older, the early mortality and late survival did not show a difference.

Hypothesis 2: Is there a delay because of a different pain perception?

There exist some hypotheses to explain the higher mortality of female patients observed in other studies [7,20]. Who analyzed Stanford type A and B dissections, hypothesized that a delay in diagnostic management may be one reason (in the IRAD-trial, the interval between symptom onset to clinic presentation was 17 hrs. in men *vs.* 22 hrs. in women, not significant). Additionally, significantly more women (40%) were later on diagnosed between 4 and 24 hrs of symptom onset (men, 30%, significant) [7].

It was also supposed by NIENABER that women were less likely to experience abrupt onset of chest or back pain, a typical sign of aortic dissection (indeed, the abrupt onset experienced 83% of women and 89% of men, significantly). Unfortunately, we could not investigate those aspects of patients' special history to a sufficient extent. To our experience, even in certified chest pain units, there are cases of delayed diagnosis so that a continuous education of medical students is necessary before their specialization.

Hypothesis 3: Are women older and do they therefore have less chance to be treated surgically

In the IRAD-Trial [7], the mean age in female patients was 66 y *vs.* 60 y in male patients (Significant). The cohort of all patients over 70 years comprised 35%, but 50% of female patients were aged above 70 years compared to 29% of men (significant). Although the mortality rate increases with age (38% in patients over 70 y, 26% in younger patients below 70 y), surgical treatment bears a lower risk (24%) compared to medical treatment (59%) for patients below 80 y of age [20]. In our study, the proportion of women above 70 years of age was threefold higher as in men (38% *vs.* 14%, and overall, women were significantly older (64 y ± 10 y) compared to men (53.4 y ± 12 y) (P=0.03). But we could observe equal mortality risk (25% women *vs.* 27% in men) despite higher age in women. Therefore, we would like to strengthen Beretta's opinion [20], that women should not be refused the chance of surgical treatment. From the author's personal experience, the oldest surviving female patient was 86 years old (and the youngest female was aged 26).

Hypothesis 4: Are women more often treated medically than surgically?

From the data of international registries, e.g. IRAD-trial: women are rather managed by medical treatment but not subjected to surgery (29% *vs.* 13%, P<0.001). Women showed significant higher mortality in surgical treatment (32% *vs.* 22%, P=0.013) because female patients are presented in a more severe status (tamponade, hypotension, altered mental status). A surgical treatment was double as often refused by women as by men (31 *vs.* 14%, P=0.04). Potentially in consideration of advanced age or comorbidity. Our study could not define the proportion of operative refusal. But surgical informed consent should comprise the information of very bad outcome of medical treatment in contrast to surgical treatment.

Hypothesis 5: Are women presented later and in a more severe clinical status?

In our study, women were presented in a severe preoperative clinical status as reflected in a EURO-Score dependent mortality rate (women: 38 *vs.* 28 in men, P=0.03 significant). The rise of one point of Euroscore lead to a significant rise of 10% mortality (Hazard ratio, 1.103, P=0.038).

In our study, women were older than men but showed the same mortality. They may benefit from a more intensive and may be a more time-demanding postoperative course (Hazard ratio, 0.849, P=0.015), that means, mortality rate lowers with 15% with each day of ICU stay.

Hypothesis 6: Do women have a worse survival?

Although women are 10 years older, reflecting their high proportion in the over 70 y- group and may have been presented in a severe clinical status, we could not observe a shorter survival. Up to 8 years postoperatively, there was no significant difference.

Conclusion

Women were significantly older and had a higher incidence for aortic type A dissection in the 7th and 8th decades. Despite higher age, gender did not influence survival.

Even with modern techniques, initial mortality remains high. After surviving the initial trauma, most patients survive the first year (98%). The survival curve declines between 5 (88%) and 10 years (50%).

In female patients, as expected, EURO-Scoring significantly reflects the risk of a severe preclinical status. In male patients, age and resternotomy had a significant influence on survival.

Even at older age, women should have the chance to be treated surgically. Aortic dissections remain a surgical challenge that demands the surgeon's ability to find the best solution for his patients' survival. In the recommendations for diagnosis and treatment on Aortic dissections, as well as in the surgeon's head, the older data should be replaced by modern experiences giving more and older female patients a chance to survive the disease, always having in the mind the patients' right for a self- determined life [21].

Limitations

We present data based on a single center experience that were analyzed retrospectively. A 10 year time period gives information about a relatively limited number of patients. Institutional data bear some risk of over-estimating and over-interpreting data. Conclusions from those data have to be made with caution.

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