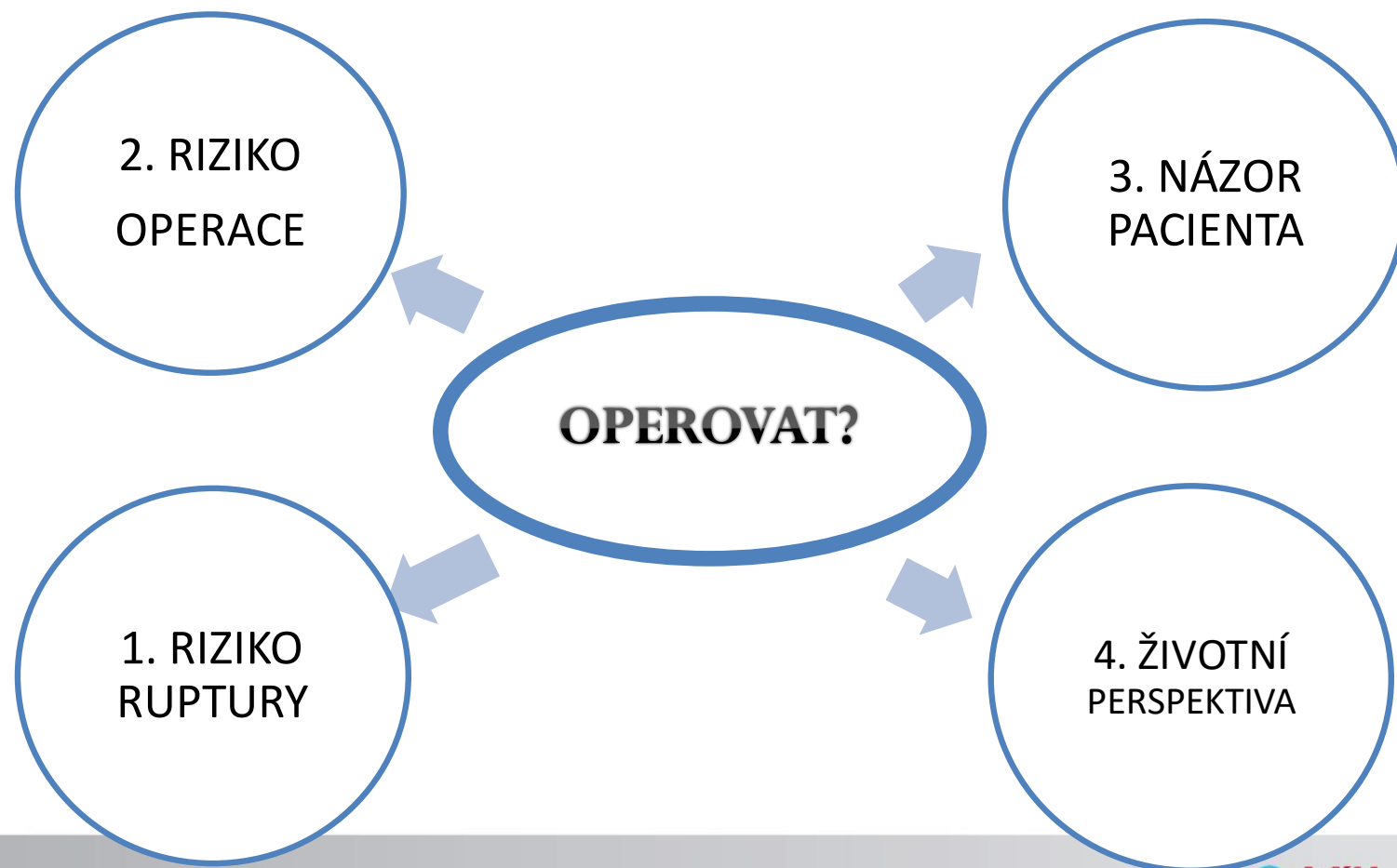


Výsledky elektivní léčby aneuryzmat břišní aorty

Mazur M., Pekař M., Chovancová T.
Víteckovická nemocnice

Výsledky elektivní léčby AAA - kdy a koho léčit?



1. RIZIKO RUPTURY

A) VELIKOST

B) TVAR

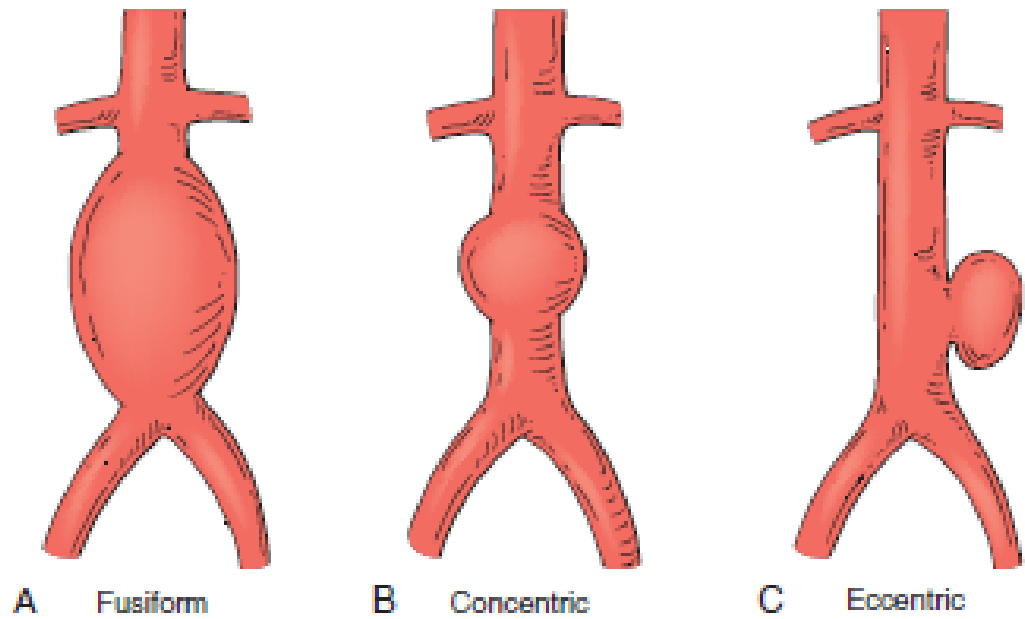
C) RŮST

A. VELIKOST

Table 130-4 Range of Potential Rupture Rates for a Given Size of Abdominal Aortic Aneurysm	
AAA Diameter (cm)	12-Month Rupture Risk (%)
3.0-3.9	0.3
4.0-4.9	0.5-1.5
5.0-5.9	1-11
6.0-6.9	11-22
>7	>30

CRONENWETT, J.L., JOHNSTON, K.V. *Rutherford's Vascular Surgery*, 2014

B. TVAR



- excentrické a sakulární AAA představují vyšší riziko ruptury než fusiformní
- pokud je AAA příliš asymetrické, má tato vlastnost na riziko ruptury stejný vliv jako průměr aneurysmatu
- CRONENWETT, J.L., JOHNSTON, K.V. Rutherford's Vascular Surgery, 2014

C. RŮST

- průměr aneurysmatu se zvětšuje o cca $1,62 \pm 0.20$ mm za rok
- rychlost růstu závisí až exponenciálně na velikosti aneurysmatu
- průměrně 3,5cm aneurysma dosáhne průměru 5,5cm za 6,2 let, zatímco 4,5 cm aneurysma dosáhne stejného průměru za 2,3 roky

- CRONENWETT, J.L., JOHNSTON, K.V. Rutherford's Vascular Surgery, 2014

C. RŮST



- rizikový faktor - rychlost růstu >1 cm/rok
- indikace k elektivnímu výkonu bez ohledu na jeho velikost

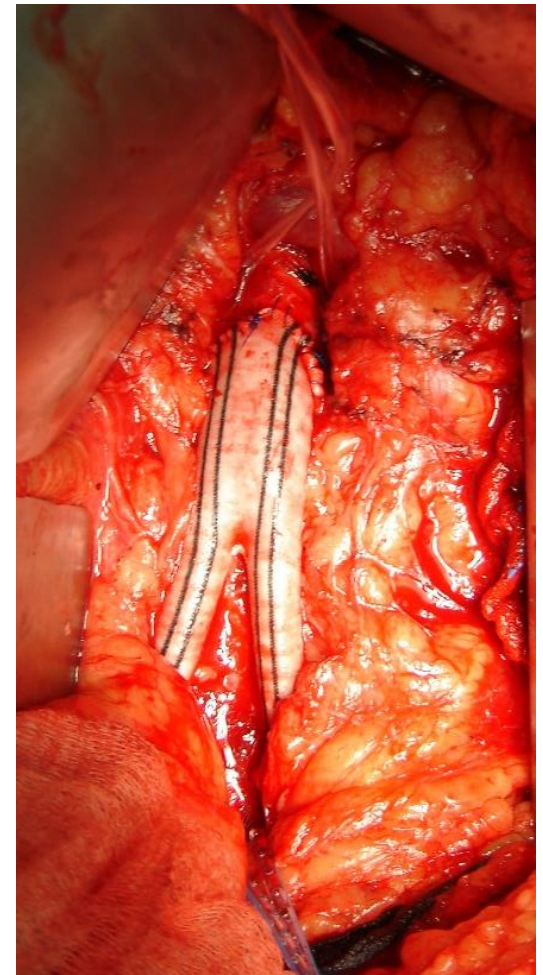
2. RIZIKO OPERACE

- **celkové - morbidita pacienta**
 - riziko operace zvyšují: vyšší věk, ženské pohlaví, onemocnění srdce, CHOPN, renální insuficience
- **lokální - morfologie AAA (juxtarenální), typ výkonu, předchozí operace**
- **zkušenost a vybavenost pracoviště - 50 výkonů**
 - perioperační mortalita - 1- 8% - dle pracoviště

- Haimovici's Vascular Surgery, 2012

3. NÁZOR PACIENTA

- zvažovat preferenci pacienta
- doporučení IIa, evidence B



- Moll F.F. et al. Management of Abdominal Aortic Aneurysms. Clinical Practice Guidelines of the ESVS. Eur J Vasc Endovasc Surg (2011) 41, S1eS58

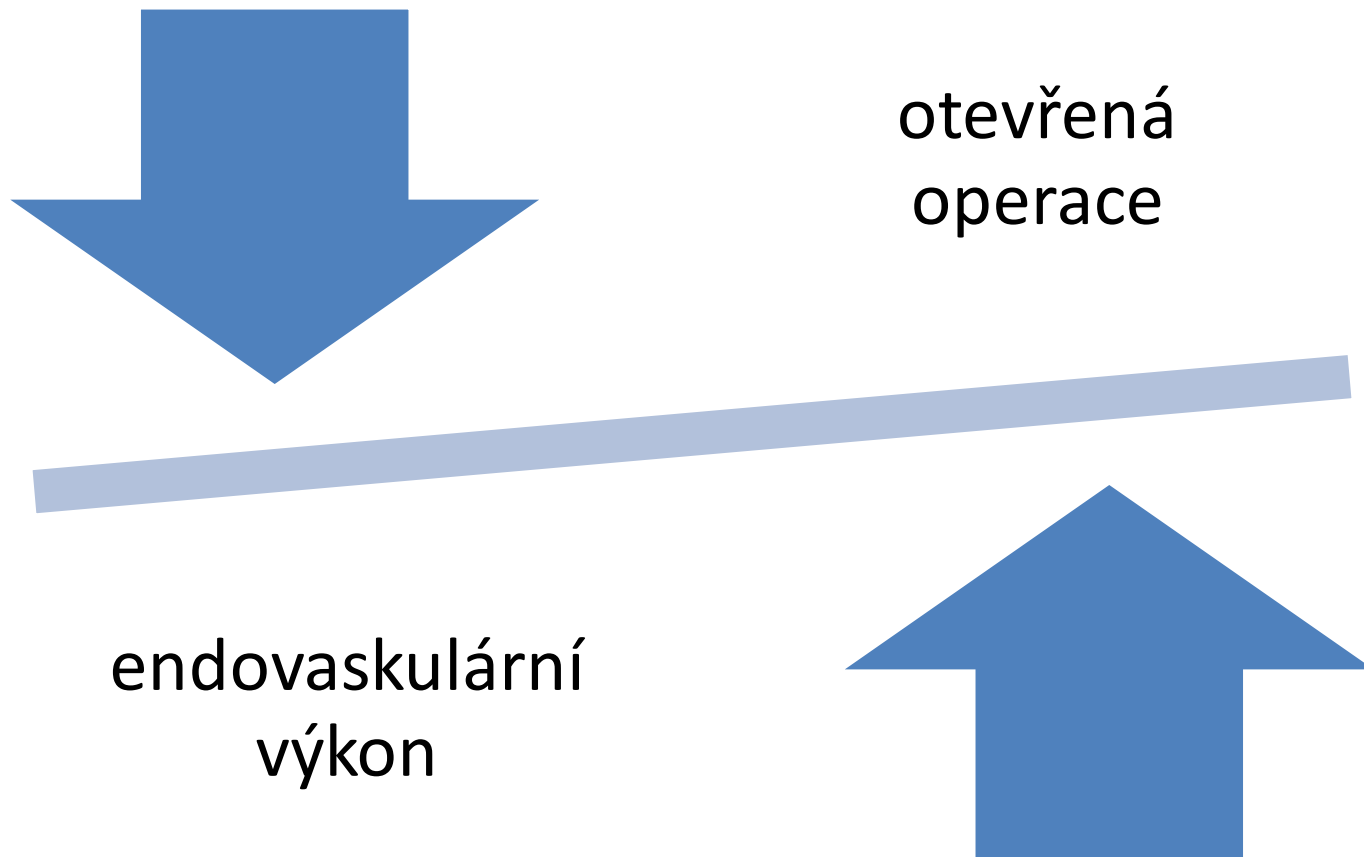
4. ŽIVOTNÍ PERSPEKTIVA

- předpoklad přežití nad 2-3 roky

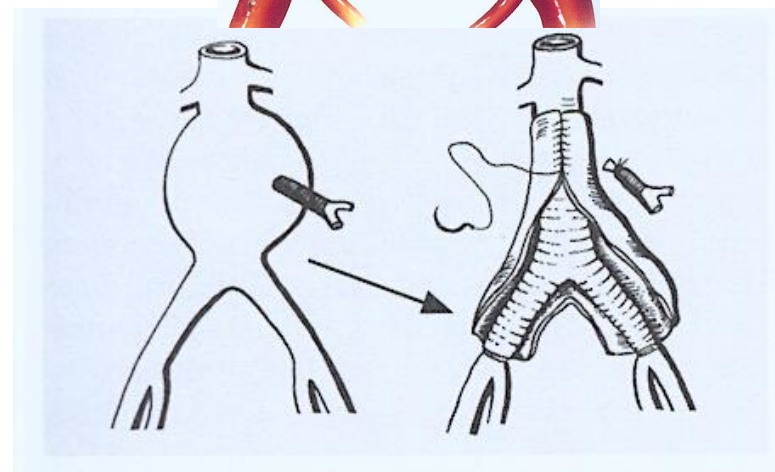
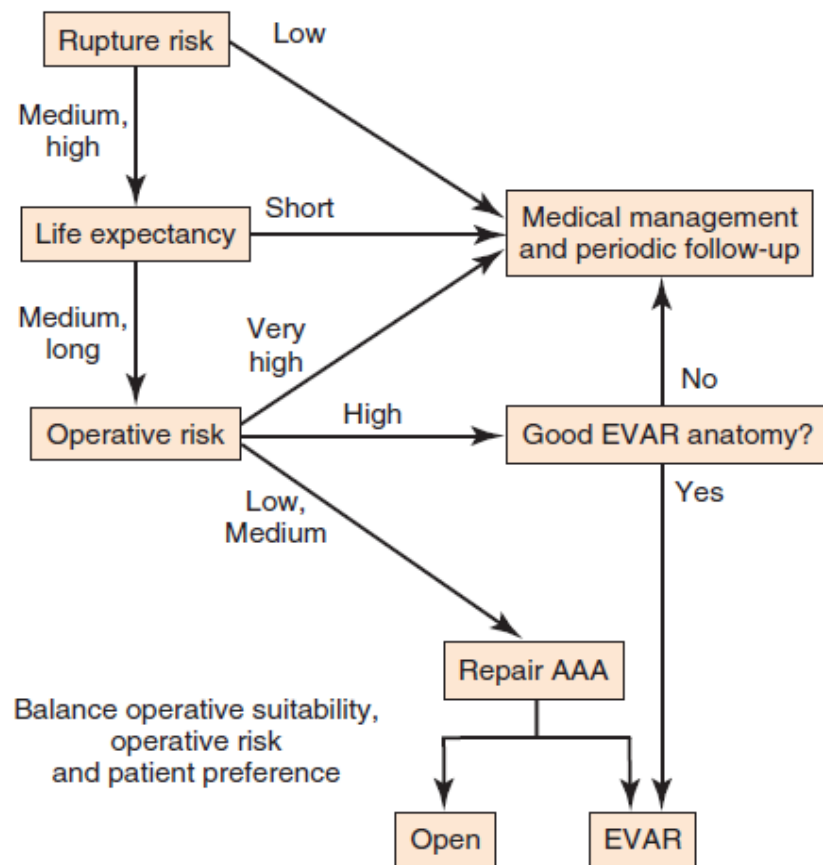
Table 130-8		Life Expectancy in Years for Patients Surviving Abdominal Aortic Aneurysm Repair by Age, Gender, and Race			
Age (Yr)	Total	MALE		FEMALE	
		White	Black	White	Black
60	13	12	11	14	13
65	11	11	10	12	11
70	10	9	8	10	10
75	8	8	7	9	8
80	8	6	6	7	6
≥85	5	4	4	5	5

- CRONENWETT, J.L., JOHNSTON, K.V. *Rutherford's Vascular Surgery*, 2014

Výsledky elektivní léčby aneuryzmat břišní aorty



MANAGEMENT AAA



CRONENWETT, J.L., JOHNSTON, K.V. *Rutherford's Vascular Surgery*, 2014

Výsledky elektivní léčby aneuryzmat břišní aorty - ESVS guidelines

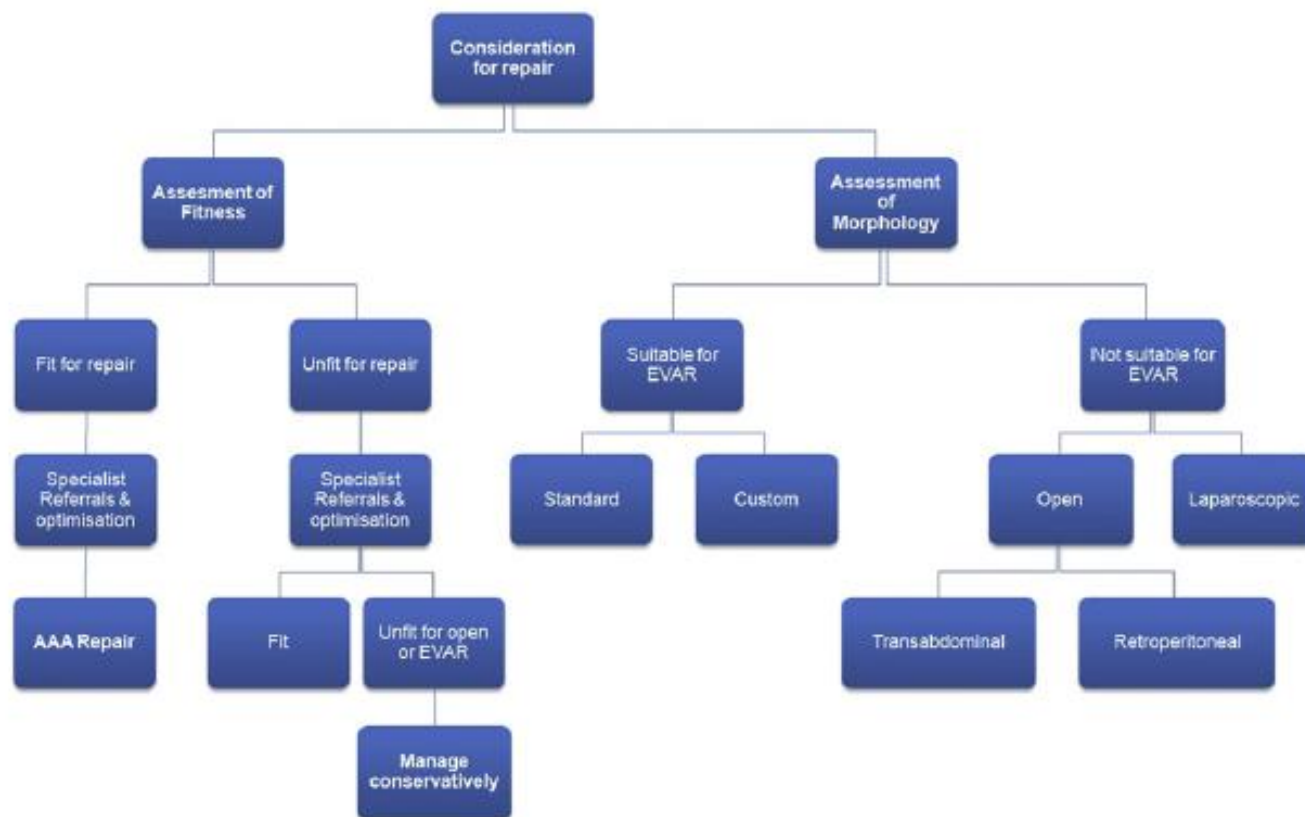


Figure 2 Management of AAA for large aneurysms (continued from Figure 1).

Výsledky elektivní léčby aneuryzmat břišní aorty - ESC guidelines

Management of asymptomatic patients with enlarged aorta or abdominal aortic aneurysm (AAA) (cont.)

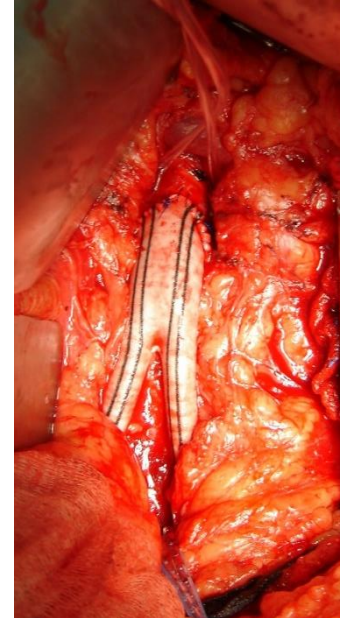
Recommendations	Class	Level
Smoking cessation is recommended to slow the AAA growth.	I	B
To reduce aortic complications in patients with small AAAs, the use of statins and ACE-inhibitors may be considered.	IIb	B
AAA repair is indicated if: AAA diameter exceeds 55 mm. Aneurysm growth exceeds 10 mm/year.	I	B
<u>If a large aneurysm is anatomically suitable for EVAR, either open or endovascular aortic repair is recommended in patients with acceptable surgical risk.</u>	I	A
If a large aneurysm is anatomically unsuitable for EVAR, open aortic repair is recommended.	I	C
In patients with asymptomatic AAA who are unfit for open repair, EVAR along with best medical treatment may be considered.	IIb	B

www.escardio.org/guidelines European Heart Journal (2014); 35:2873–2926 - doi:10.1093/eurheartj/ehu281



OTEVŘENÁ OPERACE

- OR - 1952, Dubost, EVAR - 1991, Parodi
 - velká centra - peroperační mortalita 1-4%
 - komplikace 15-30%
 - časně - krvácení, deklamping hypotenze, poranění ureteru, RI, ischémie DK, ischemická kolitida, infekce graftu
 - pozdní - pseudoaneurysma, infekce graftu, aortoenterická píštěl, sexuální dysfunkce
 - **operace v centrech s mortalitou < 5%**
- Haimovici's Vascular Surgery, 2012

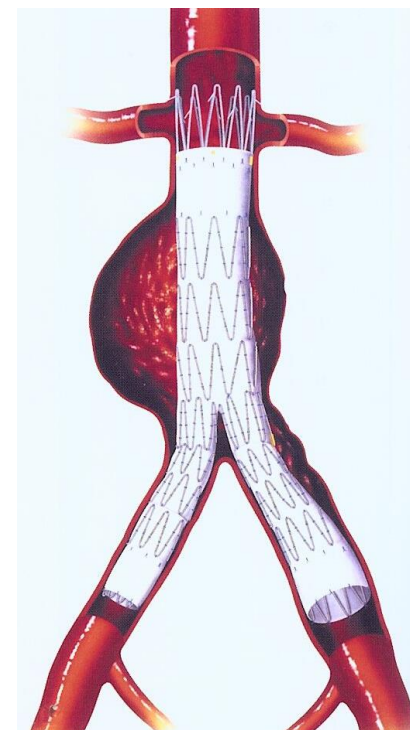


Endovascular versus Open Repair of Abdominal Aortic Aneurysm

The United Kingdom EVAR Trial Investigators*

N Engl J Med 2010; 362:1863-1871 | [May 20, 2010](#) | DOI: 10.1056/NEJMoa0909305

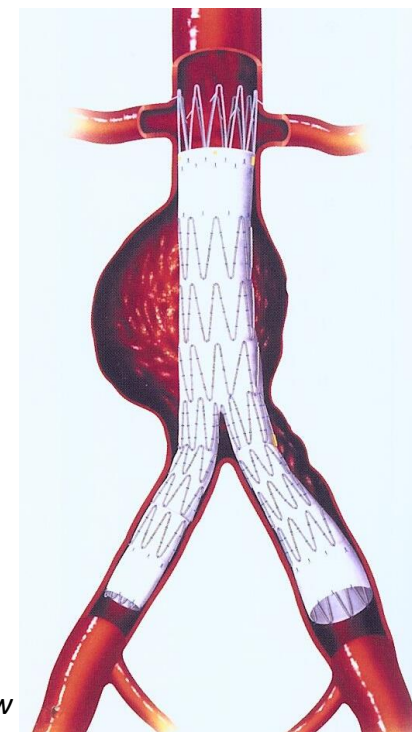
- EVAR I
- pacienti zařazovaní od 1.9.1999 do 31.8. 2004
- sledování do 31.12. 2009,
- průměrný follow up 8 let
- 1252 pacientů



EVAR – 1

1252 PACIENTŮ

	EVAR	OS
POČET PACIENTŮ	626	626
30 DENNÍ MORTALITA	1,8%	4,3%
MORTALITA	5,5%	5,7%
RUPTURA	25	0
KOMPLIKACE	4,39%	2,86%



GREENGALGH, R.M.; Endovascular versus Open Repair of Abdominal Aortic Aneurysm. *The New England Journal of Medicine* [online]. 2010. Dostupný
<http://www.nejm.org/doi/full/10.1056/NEJMoa0909305#t=article>

J Vasc Surg. 2010 Mar;51(3):577-83, 583.e1-3. doi: 10.1016/j.jvs.2009.10.101. Epub 2010 Jan 4.

Long-term outcomes and resource utilization of endovascular versus open repair of abdominal aortic aneurysms in Ontario.

Jetty P¹, Hebert P, van Walraven C.

- randomizovaná studie, 6461 pacientů
- peroperační mortalita signifikantně nižší u EVAR
- **dlouhodobá mortalita stejná**
- signifikantně více zobrazovacích metod u EVAR
- **EVAR vyšší počet reintervencí**

Long-Term Comparison of Endovascular and Open Repair of Abdominal Aortic Aneurysm

Frank A. Lederle, M.D., Julie A. Freischlag, M.D., Tassos C. Kyriakides, Ph.D.,
Jon S. Matsumura, M.D., Frank T. Padberg, Jr., M.D., Ted R. Kohler, M.D.,
Panagiotis Kougias, M.D., Jessie M. Jean-Claude, M.D.,
Dolores F. Cikrit, M.D., and Kathleen M. Swanson, M.S., R.Ph.,
for the OVER Veterans Affairs Cooperative Study Group*

- randomizovaná studie z r. 2012, 881 pacientů
- peroperační mortalita 0,5 vs 3% p=0,004
- nad 2 roky - rozdíl v mortalitě není
- ruptury - 6 ruptur u EVAR, 0 u OR p=0,03
- do 70 let EVAR delší přežívání p=0,04
- nad 70 let u OS delší přežívání p=0,06
- není rozdíl v počtu sekundárních intervencí, 9 konverzí u EVAR

Br J Surg. 2013 Jun;100(7):863-72. doi: 10.1002/bjs.9101. Epub 2013 Mar 8.

Systematic review and meta-analysis of the early and late outcomes of open and endovascular repair of abdominal aortic aneurysm.

Stather PW¹, Sidloff D, Dattani N, Choke E, Bown MJ, Sayers RD.

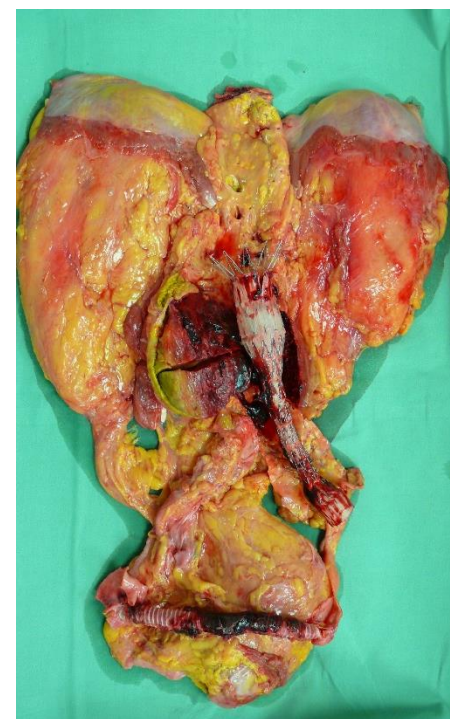
- metaanalýza, 25078 a 27142 pacientů
- peroperační mortalita 1,3 vs. 4,7% p<0,001
- 2 letá mortalita 14,3 vs. 15,2% p=0,17
- 4 letá mortalita 34,7 vs. 33,8% p=0,3
- EVAR - signifikatně více intervencí p=0,003
- EVAR - signifikantně více ruptur p=0,001
- **Dlouhodobě EVAR nepřináší benefit**

J Vasc Surg. 2013 Jun;57(6):1676-83, 1683.e1. doi: 10.1016/j.jvs.2013.02.013.

Mortality and reintervention following elective abdominal aortic aneurysm repair.

Qadura M¹, Pervaiz F, Harlock JA, Al-Azzoni A, Farrokhvar F, Kahnamoui K, Szalay DA, Rapanos T.

- metaanalýza, 2783 pac.
- peroperační mortalita 1,2 vs. 3,2%
- reintervence (heterogenita) 18,9 vs. 9,3%
- **Dlouhodobá mortalita stejná**





Endovascular versus open repair of abdominal aortic aneurysm in 15-years' follow-up of the UK endovascular aneurysm repair trial 1 (EVAR trial 1): a randomised controlled trial



Rajesh Patel, Michael J Sweeting, Janet T Powell, Roger M Greenhalgh, for the EVAR trial investigators*

Summary

Lancet 2016; 388: 2366–74

Published Online
October 12, 2016

Background Short-term survival benefits of endovascular aneurysm repair (EVAR) versus open repair of intact abdominal aortic aneurysms have been shown in randomised trials, but this early survival benefit is lost after a few years. We investigated whether EVAR had a long-term survival benefit compared with open repair.

Findings We recruited 1252 patients between Sept 1, 1999, and Aug 31, 2004. 25 patients (four for mortality outcome) were lost to follow-up by June 30, 2015. Over a mean of 12·7 years (SD 1·5; maximum 15·8 years) of follow-up, we recorded 9·3 deaths per 100 person-years in the EVAR group and 8·9 deaths per 100 person-years in the open-repair group (adjusted hazard ratio [HR] 1·11, 95% CI 0·97–1·27, $p=0\cdot14$). At 0–6 months after randomisation, patients in the EVAR group had a lower mortality (adjusted HR 0·61, 95% CI 0·37–1·02 for total mortality; and 0·47, 0·23–0·93 for aneurysm-related mortality, $p=0\cdot031$), but beyond 8 years of follow-up open-repair had a significantly lower mortality (adjusted HR 1·25, 95% CI 1·00–1·56, $p=0\cdot048$ for total mortality; and 5·82, 1·64–20·65, $p=0\cdot0064$ for aneurysm-related mortality). The increased aneurysm-related mortality in the EVAR group after 8 years was mainly attributable to secondary aneurysm sac rupture (13 deaths [7%] in EVAR vs two [1%] in open repair), with increased cancer mortality also observed in the EVAR group.

Interpretation EVAR has an early survival benefit but an inferior late survival compared with open repair, which needs to be addressed by lifelong surveillance of EVAR and re-intervention if necessary.



Endovascular versus open repair of abdominal aortic aneurysm in 15-years' follow-up of the UK endovascular aneurysm repair trial 1 (EVAR trial 1): a randomised controlled trial



Rajesh Patel, Michael J Sweeting, Janet T Powell, Roger M Greenhalgh, for the EVAR trial investigators*

Summary

Lancet 2016; 388: 2366–74

Published Online
October 12, 2016

Background Short-term survival benefits of endovascular aneurysm repair (EVAR) versus open repair of intact abdominal aortic aneurysms have been shown in randomised trials, but this early survival benefit is lost after a few years. We investigated whether EVAR had a long-term survival benefit compared with open repair.

	Endovascular repair (N=626)		Open repair (N=626)		Hazard ratio (95% CI)		p value†
	n/N (%)	Rate per 100 person-years	n/N (%)	Rate per 100 person-years	Unadjusted	Adjusted*	
Total mortality							
All patients	466/626 (74%)	9.3	444/626 (71%)	8.9	1.05 (0.92–1.19)	1.11 (0.97–1.27)	0.14
0–6 months	26/626 (4%)	8.5	45/626 (7%)	15.0	0.57 (0.35–0.92)	0.61 (0.37–1.02)	0.06
>6 months to 4 years	126/600 (21%)	6.7	116/581 (20%)	6.3	1.07 (0.83–1.38)	1.13 (0.87–1.47)	0.35
>4–8 years	135/474 (28%)	8.3	129/464 (28%)	8.0	1.03 (0.81–1.31)	1.07 (0.83–1.37)	0.62
>8 years	179/339 (53%)	14.9	154/333 (46%)	12.7	1.18 (0.95–1.47)	1.25 (1.00–1.56)	0.048
Aneurysm-related mortality							
All patients	56/626 (9%)	1.1	45/626 (7%)	0.9	1.24 (0.84–1.83)	1.31 (0.86–1.99)	0.21
0–6 months	14/626 (2%)	4.6	30/626 (5%)	10.0	0.46 (0.24–0.87)	0.47 (0.23–0.93)	0.031
>6 months to 4 years	12/599 (2%)	0.6	8/581(1%)	0.4	1.48 (0.60–3.62)	1.46 (0.56–3.83)	0.44
>4–8 years	14/474 (3%)	0.9	4/464 (1%)	0.2	3.46 (1.14–10.52)	3.11 (0.99–9.72)	0.05
>8 years	16/339 (5%)	1.3	3/333 (1%)	0.2	5.50 (1.60–18.89)	5.82 (1.64–20.65)	0.0064

*Hazard ratios adjusted for age, sex, maximum aneurysm diameter, forced expiratory volume in 1 s, log creatinine, statin use, body-mass index, smoking status, systolic blood pressure and total cholesterol; 77 individuals excluded due to missing data. †p value adjusted for covariates.

Table 1: Deaths from any cause and aneurysm-related causes, according to time since randomisation in the intention-to-treat population

Meta-analysis of individual-patient data from EVAR-1, DREAM, OVER and ACE trials comparing outcomes of endovascular or open repair for abdominal aortic aneurysm over 5 years

J. T. Powell¹, M. J. Sweeting², P. Ulug¹, J. D. Blankensteijn³, F. A. Lederle⁴, J.-P. Becquemin⁵ and R. M. Greenhalgh¹, on behalf of the EVAR-1, DREAM, OVER and ACE Trialists

¹Vascular Surgery Research Group, Imperial College London, London, and ²Department of Public Health and Primary Care, University of Cambridge, Cambridge, UK, ³Department of Surgery, VU Medical Centre, Amsterdam, The Netherlands, ⁴Department of Medicine, VA Medical Centre, Minneapolis, Minnesota, USA, and ⁵Vascular Institute of Paris East, Hôpital Privé Paul d'Egine, Champigny, Université, Paris-Est Créteil, Créteil, France

Meta-analysis of individual-patient data from EVAR-1, DREAM, OVER and ACE trials comparing outcomes of endovascular or open repair for abdominal aortic aneurysm over 5 years

Methods: An individual-patient data meta-analysis of four multicentre randomized trials of EVAR *versus* open repair was conducted to a prespecified analysis plan, reporting on mortality, aneurysm-related mortality and reintervention.

Results: The analysis included 2783 patients, with 14 245 person-years of follow-up (median 5.5 years). Early (0–6 months after randomization) mortality was lower in the EVAR groups (46 of 1393 *versus* 73 of 1390 deaths; pooled hazard ratio 0.61, 95 per cent c.i. 0.42 to 0.89; $P = 0.010$), primarily because 30-day operative mortality was lower in the EVAR groups (16 deaths *versus* 40 for open repair; pooled odds ratio 0.40, 95 per cent c.i. 0.22 to 0.74). Later (within 3 years) the survival curves converged, remaining converged to 8 years. Beyond 3 years, aneurysm-related mortality was significantly higher in the EVAR groups (19 deaths *versus* 3 for open repair; pooled hazard ratio 5.16, 1.49 to 17.89; $P = 0.010$). Patients with moderate renal dysfunction or previous coronary artery disease had no early survival advantage under EVAR. Those with peripheral artery disease had lower mortality under open repair (39 deaths *versus* 62 for EVAR; $P = 0.022$) in the period from 6 months to 4 years after randomization.

Conclusion: The early survival advantage in the EVAR group, and its subsequent erosion, were confirmed. Over 5 years, patients of marginal fitness had no early survival advantage from EVAR compared with open repair. Aneurysm-related mortality and patients with low ankle:brachial pressure index contributed to the erosion of the early survival advantage for the EVAR group. Trial registration numbers: EVAR-1, ISRCTN55703451; DREAM (Dutch Randomized Endovascular Aneurysm Management), NCT00421330; ACE (Anévrisme de l'aorte abdominale, Chirurgie *versus* Endoprothèse), NCT00224718; OVER (Open *Versus* Endovascular Repair Trial for Abdominal Aortic Aneurysms), NCT00094575.

Presented to the Charing Cross International Symposium, London, UK, April 2016

Paper accepted 26 September 2016

Published online in Wiley Online Library (www.bjs.co.uk). DOI: 10.1002/bjs.10430

Meta-analysis of individual-patient data from EVAR-1, DREAM, OVER and ACE trials comparing outcomes of endovascular or open repair for abdominal aortic aneurysm over 5 years

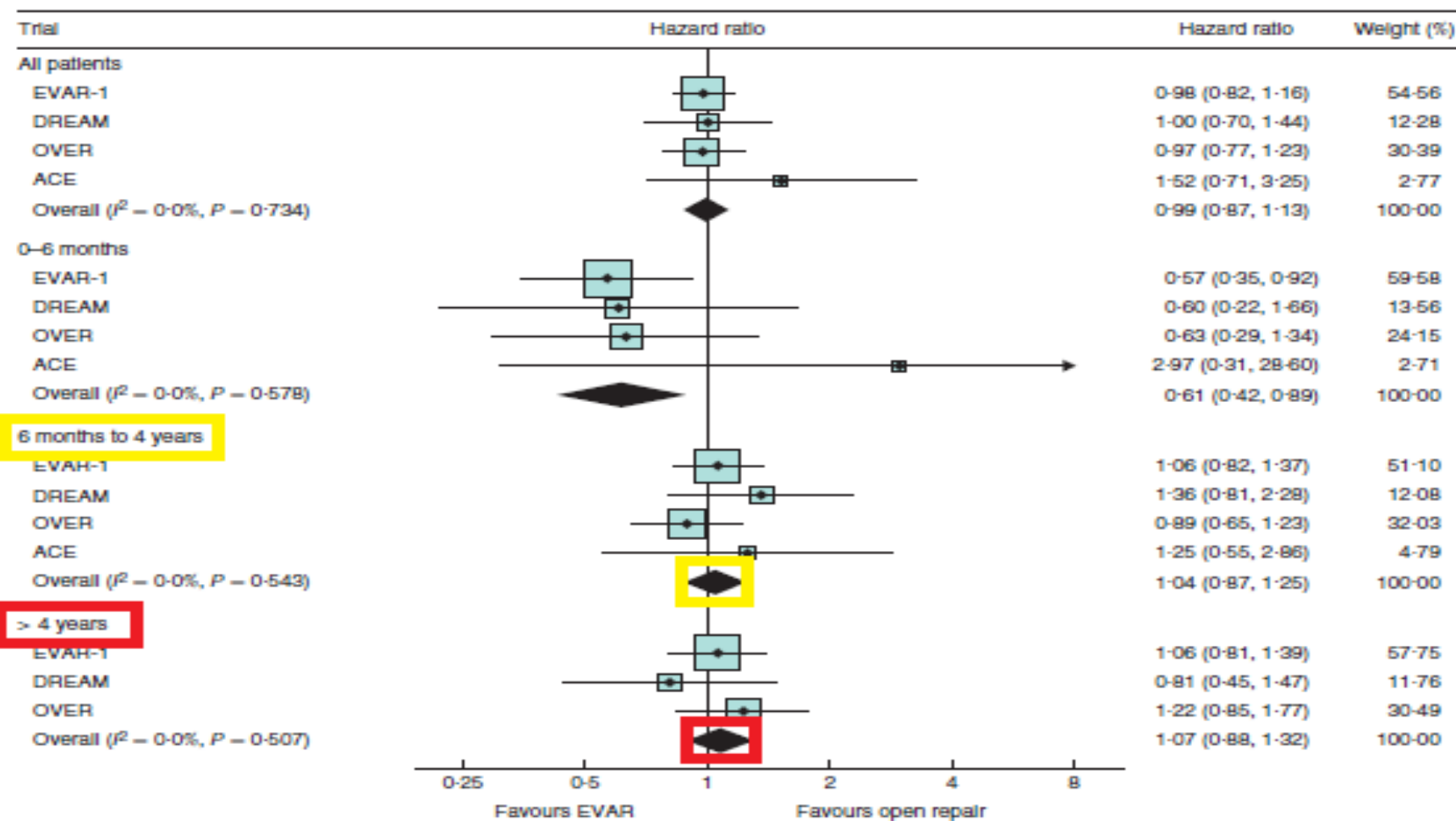


Fig. 2 Unadjusted hazard ratios, with 95 per cent confidence intervals, for total mortality overall and at 0-6 months, 6 months to 4 years and more than 4 years since randomization. EVAR, endovascular aneurysm repair

Meta-analysis of individual-patient data from EVAR-1, DREAM, OVER and ACE trials comparing outcomes of endovascular or open repair for abdominal aortic aneurysm over 5 years

Discussion

These four randomized trials, in Europe and the USA, provide the best evidence for the early survival advantage offered by EVAR rather than open repair. Patients prefer EVAR, the less invasive method of AAA repair, which has been adopted widely, and the majority of elective repairs are now performed using EVAR^{8,19,20}. This meta-analysis, over a 5-year time horizon, confirms that, overall, there is an early survival advantage for EVAR, which is lost within 3 years of randomization, so that the life-years saved from EVAR over 5 years are minimal. Between 0 and 6 months after randomization, total and aneurysm-related mortality rates were lower for the EVAR group, mainly because of the 2.5-fold lower 30-day operative mortality in this group. However, after this interval, the early EVAR group advantage was eroded progressively. By 3 years after aneurysm repair, aneurysm-related mortality was five times higher in the EVAR group (mainly due to secondary rupture or reinterventions) and this is likely to have contributed to the 'catch-up' in mortality.

four trials. The overall rates of reintervention reported were higher in the EVAR group than in the open repair group for all trials (Table 1). The risk of reintervention

Výsledky elektivní léčby AAA - vlastní zkušenost

AAA ve VTN 1/2014 – 9/2017 94 operací

	rozmezí	průměr
věk	51-83	70,8
šíře AAA (mm)	37-110	64
krevní ztráty (ml)	200-4000	1073

Perioperační mortalita (1x)

1,1%

Morbidita

12%

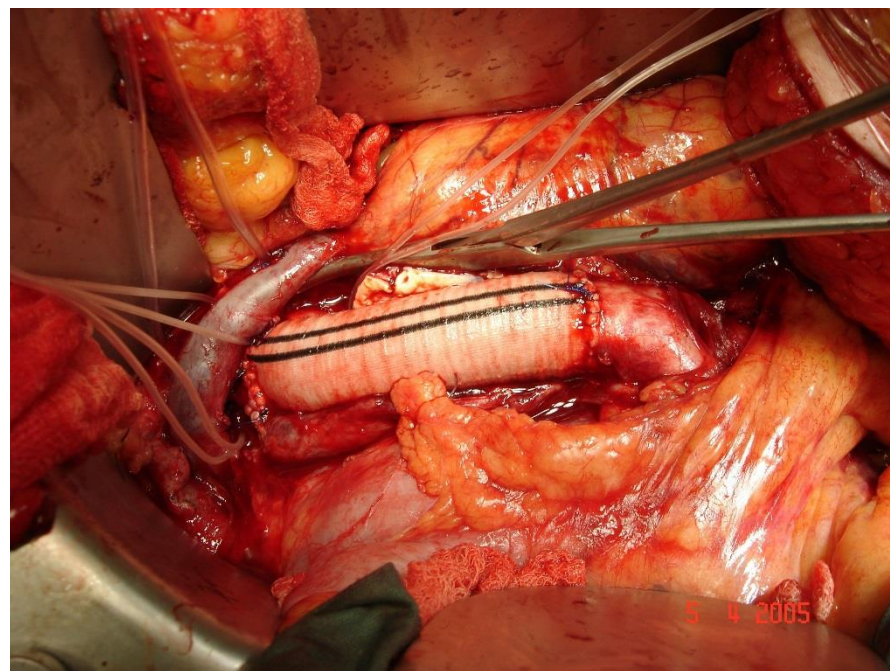
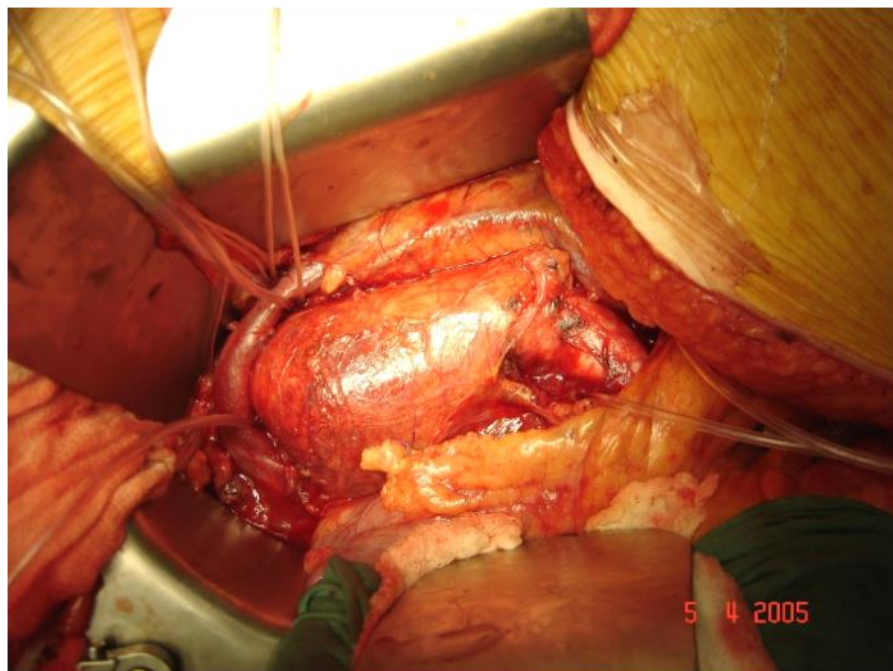
(4x pneumonie, 1x resp. insuf s UPV, 1x renální insuf, 1x klostr. průjem, 1x bronchitida + delirium, 1x paréza GIT, 2x delirium)

Časné chirurgické komplikace

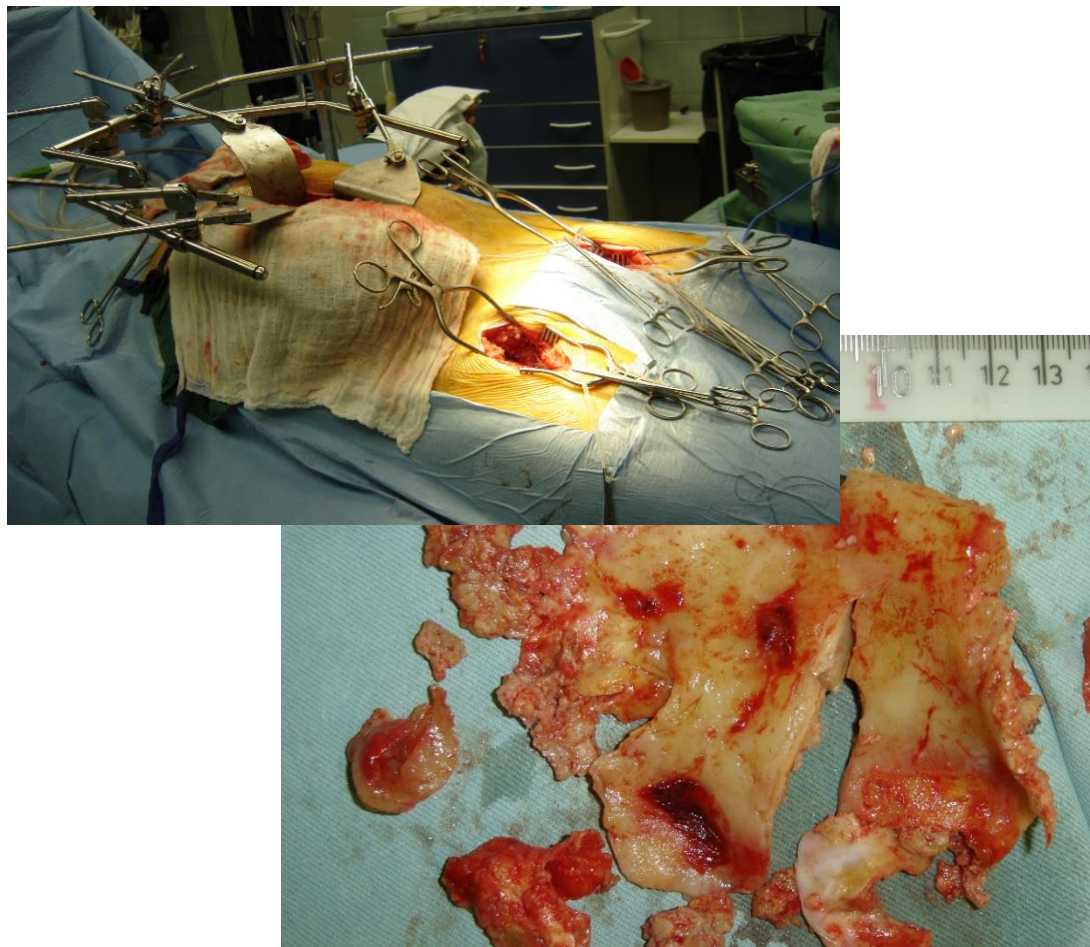
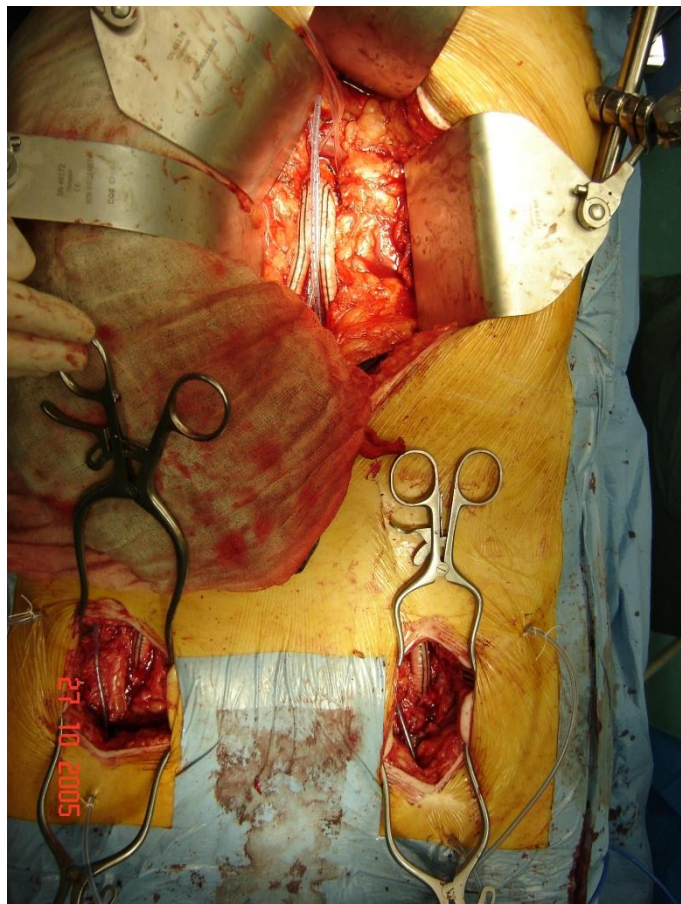
3,2%

(sutura ureteru, resutura kůže, reamputace pahýlu stehna)

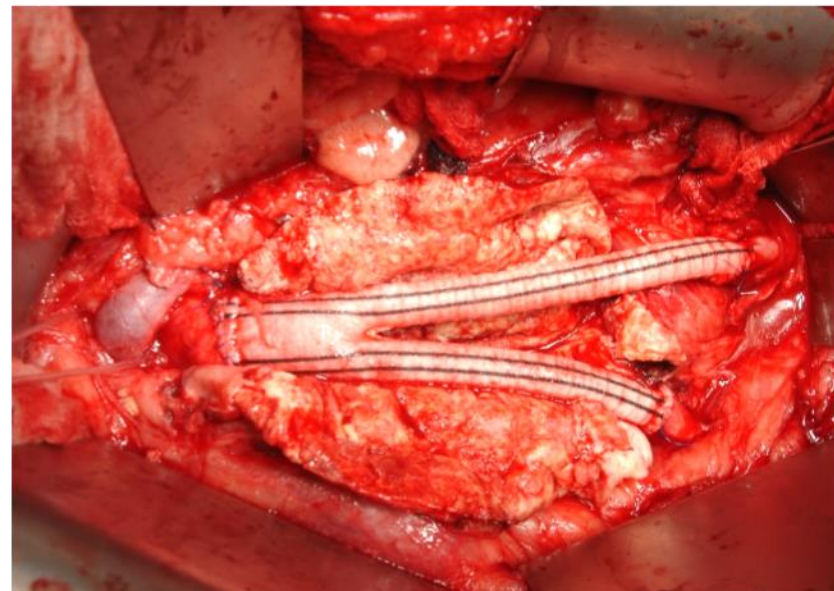
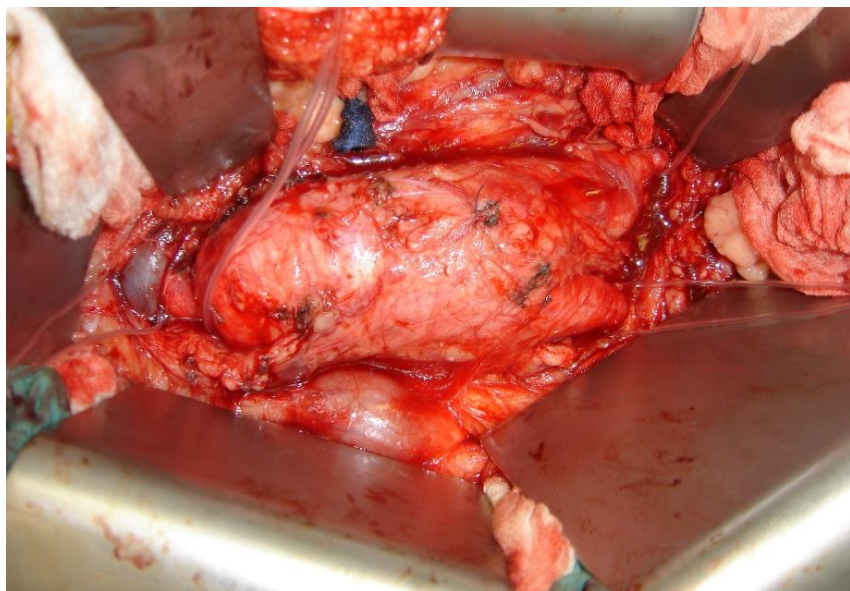
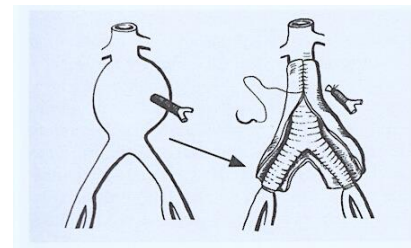
Aortoaortální náhrada – 58 (62%)



Aortobifemorální náhrada – 33 (35%)



Aortobiilická náhrada – 3 (3%)



Výsledky elektivní léčby AAA – kdy a koho léčit?

Závěr I.

	<u>Preference</u>
• mortalita - peroperační - dlouhodobá - dlouhodobá k AAA • reoperace, intervence, ruptury • kvalita života (dispenzarizace, vyšetření) • ekonomika, rentabilita (300 000 vs. 15 000Kč) • guidelines – EBM • názor pacienta	- EVAR - operace $\geq$ EVAR - operace - operace - operace = EVAR? - operace - operace = EVAR? - EVAR
• „ZDRAVÝ“ PACIENT	- ???

Výsledky elektivní léčby AAA – kdy a koho léčit?

Závěr II.

- z dlouhodobého hlediska EVAR nepřináší benefit
- multidisciplinární přístup (ne konkurenční)
- řešení na „míru“
- kvalita pracoviště
- nové technologie - trend k EVAR



Děkuji za pozornost