Langenbecks Arch Surg (2008) 393:281–287
DOI 10.1007/s00423-008-0284-8

EVIDENCE-BASED SURGERY

Prospective randomized controlled trial to evaluate "fast-track" elective open infrarenal aneurysm repair

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Received: 19 December 2007 / Accepted: 17 January 2008 / Published online: 14 February 2008

Abstract
Background and aims Fast-track programs have been introduced in many surgical fields to minimize postoperative morbidity and mortality. Morbidity after elective open infrarenal aneurysm repair is as high as 30%; mortality ranges up to 10%. In terms of open infrarenal aneurysm repair, no randomized controlled trials exist to introduce and evaluate such patient care programs.
Materials and methods This study involved prospective randomization of 82 patients in a "traditional" and a "fast-track" treatment arm. Main differences consisted in preoperative bowel washout (none vs. 3 l cleaning solution) and analgesia (patient controlled analgesia vs. patient controlled epidural analgesia). Study endpoints were morbidity and mortality, need for postoperative mechanical ventilation, and length of stay (LOS) on intensive care unit (ICU).
Results The need for assisted postoperative ventilation was significantly higher in the traditional group (33.3% vs. 5.4%; p=0.011). Median LOS on ICU was shorter in the fast-track group, 41 vs. 20 h. The rate of postoperative medical complications was significantly lower in the fast-track group, 16.2% vs. 35.7% (p=0.045).
Conclusion We introduced and evaluated an optimized patient care program for patients undergoing open infrarenal aortic aneurysm repair which showed a significant advantage for "fast-track" patients in terms of postoperative morbidity.

German Society of Surgery, Surgical Forum 2008, Best of Abstracts.

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Keywords Fast track · Aortic aneurysm repair

Introduction

Today, endovascular (ER) and open repair (OR) are provided in the treatment of infrarenal aortic aneurysms. However, there is no beneficial impact of ER on overall morbidity and mortality when similar preoperative medical risk factors exist [1]. Hence, open repair of infrarenal aortic aneurysm remains as standard therapy in patients who are fit for surgery. Despite advances in surgical procedures and perioperative care, patients undergoing major surgical procedures are still threatened by postoperative complications, such as myocardial ischemia, thrombembolism, and pneumonia. Risk factors influencing outcome of open infrarenal aortic aneurysm repair are age >75 years, preexisting history of cardiac ischemia, chronic obstructive disease, and renal insufficiency [2]. In terms of elective open aortic aneurysm surgery, the 30-day mortality rates range from 6% to 8% and severe medical complications such as cardiac ischemia, pneumonia, and acute renal failure occur in up to 59% [3, 4]. After open repair, the median duration of ventilator use is 1.3 days and the median length of stay on intensive care unit (ICU) is 3.2 days [5]. Single interventions do not seem to be able to further improve outcome in these patients. Hence, attention nowadays is being directed toward multimodal therapies that reduce surgical stress, optimize postoperative analgesia, and adjust postoperative care in order to reduce

complication rates after major surgical procedures [6]. So-called fast-track recovery programs have been proposed for colorectal resections [7], cholecystectomy [8], and radical prostatectomy [9]. With respect to elective open infrarenal aortic aneurysm repair, no fast-track patient care program has been proposed nor has it been evaluated in a prospective randomized controlled trial. Therefore, we have developed an optimized perioperative treatment (fast-track) protocol for elective open infrarenal aortic aneurysm repair and have conducted a pilot study in a prospective randomized controlled manner to evaluate this program compared to "traditional" treatment.

Materials and methods

Study design

The study was designed as a monocentric, randomized, controlled, and prospective pilot study. The study protocol was approved by the local ethics committee and was conducted according to the principles of the Declaration of Helsinki. After given written informed consent, patients were randomly assigned to the two treatment arms using a randomized block design prepared by the Department of Biometry, University of Ulm.

Inclusion/exclusion criteria

All patients who were admitted with infrarenal aortic aneurysm and who had indication for elective open repair were eligible for the study. After given written informed consent, patients were randomly assigned to either the traditional or the fast-track patient management. Patients were excluded if one of the following conditions was given: withdrawal of informed consent, clinical signs of infection (fever, leukocytosis) on admission, contraindications for epidural anesthesia (e.g., coagulopathy), and neuromuscular disorder that did not allow proper postoperative physiotherapy. Intraoperative suprarenal clamping also led to exclusion from the study.

Study endpoints

Study endpoints were morbidity and mortality, length of stay on intensive care unit, need for postoperative mechanical ventilation, and day of discharge.

Definition of variables

Cardiovascular

Myocardial ischemia was suspected and documented if two of the following signs were noticed: chest pain and/or electrocardiogram (ECG) changes and/or elevated heart enzymes.

Respiratory

Pneumonia was confirmed if the patient showed clinical and radiological signs of infection (temperature >38°C, infiltration on chest X-rays) that required administration of antibiotics.

Renal failure

Acute renal failure was confirmed if urine output was <40 ml/h and serum creatinine increased over 130 μmol/l in the postoperative course and the patient needed administration of diuretics.

Gastrointestinal

Functional bowel obstruction (paralytic ileus) was confirmed if vomiting was present or the patient was not able to take oral food and horizontal fluid levels were documented on erect abdominal X-ray.

Infective

Urinary tract infection was confirmed if bacteria were present in the urine probe and antibiotic medication was administered; intravenous (i.v.) line infection was confirmed with positive bacterial probes and elevated temperature to 39°C (Table 1).

Table of randomization

Eighty-two patients have been randomized in our study. Three patients in the fast-track group were excluded due to withdrawal of informed consent, suprarenal aortic cross clamping, and dislocation of the epidural catheter, respectively. Forty-two patients were assigned to the traditional and 37 to the fast-track group. Analysis was performed per protocol (Fig. 1).

Perioperative patient management

In both groups, heat loss was prevented by administration of warm i.v. fluids and external heating using air heaters in the preparation room and on the operative table. Major differences consisted in preoperative fasting, bowel washout, start of enteral feeding, and pain control.

Traditional treatment

Traditional perioperative management of patients undergoing open infrarenal aortic aneurysm repair in our institution

Table 1 Definition of variables: if two or more criteria in each category were documented, the medical complication was confirmed

Organ system	Criteria for failure
Myocardial ischemia	Chest pain
	ECG signs
	Elevated heart enzymes
Dysrhythmia	Heart rate <45 bpm or >80 bpm
	AV blockage confirmed on ECG
	Need for antiarrhythmic medication
Renal	Urine output <40 ml/h
	Serum creatinine >130 μmol/l
	Need for diuretic therapy
Pneumonia	Infiltration on chest x-ray
	Elevated WCC- or C-reactive protein
	Administration of antibiotics
Functional bowel obstruction (paralytic ileus)	Vomiting, need for gastric tube
	Horizontal fluid levels on abdominal X-ray
Urinary tract infection	Bacteria in urine probe
	Administration of antibiotics
Intravenous line infection	Temperature >39°C
	Positive blood culture

consists of the following measurements: preoperative patient education, preoperative fasting for 6 h, and bowel washout; pain control is usually achieved by postoperative administration of i.v. opioids (piritramide) in a patient controlled manner (patient controlled analgesia). Apart from that, patients receive medication with nonsteroidal anti-inflammatory drugs (NSAIDs) (diclophenac 75 mg twice daily + metamizole 1 g, i.v., four times daily). Gastric tube is removed if secretion is less than 300 ml/24 h. Enteral feeding starts from the second postoperative day after onset of bowel movements; i.v. fluids in the early postoperative period are set to 3,000 ml/24 h.

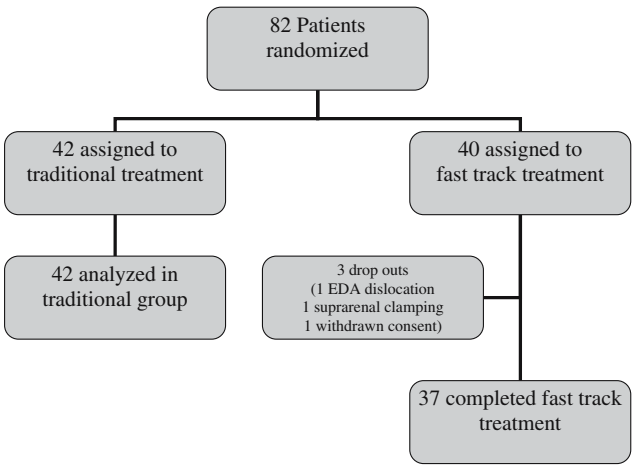

Fig. 1 Randomization and outcomes. Eighty-two patients were randomized—42 were assigned to traditional and 40 to fast-track treatment; in the fast-track treatment, three patients dropped out so that 37 patients completed fast-track treatment. *EDA* epidural anesthesia

"Fast-track regimen"

The introduced fast-track regimen includes preoperative patient education identical to the traditional management; preoperative fasting is limited to 2 h preoperatively and no bowel washout is performed. Pain control was realized using a preoperatively inserted epidural catheter which was placed in the intervertebral spaces at the level between T7 and T10 with the loss-of-resistance technique. Patients received 10 ml of ropivacaine 1% preoperatively followed by the administration of ropivacaine 0.2% and sufentanil (2 μg/ml) postoperatively in a patient controlled manner (patient controlled epidural analgesia, PCEA) accompanied by NSAIDs. Enteral feeding and ambulation started on the evening of the operation. The gastric tube is removed at the end of operation; i.v. fluids are restricted to 1,000 ml/24 h (Table 2).

Statistical analysis

The primary analysis was conducted per protocol. For discrete variables, absolute and relative frequencies are given. For continuous frequencies, median values and range are applied. To calculate significances of morbidity/mortality and postoperative complications in the treatment groups and the subgroups, Fisher's exact test was used. Values of $p<0.05$ were regarded to be significant. Statistical analysis was performed in collaboration with the Department of Biometry using the computer program SigmaStat.

Patient characteristics

The two treatment groups were similar with respect to age, sex, aneurysm diameter, and American Society of Anesthesiologists (ASA) score. In our institution, the surgical

Table 2 Detailed overview over the conservative and fast-track regimen

	Traditional	Fast-track
Bowel preparation	Washout	None
Preoperative fasting	6 h	2 h
Pain control	PCA + NSAIDs	PCEA + NSAIDs
Temperature of OR	18°C	22°C
Removal of gastric tube	<300 ml/24 h	End of operation
Start of enteral feeding	After 2–3 days	Evening of operation
Intravenous fluids	3,000 ml/24 h	1,000 ml/24 h
Mobilization	1. pod	Evening of operation

PCA Patient controlled analgesia, *NSAID* nonsteroidal anti-inflammatory drugs, *PCEA* patient controlled epidural analgesia

approach to the infrarenal aorta is achieved trans- and retroperitoneally; clamping time did not significantly differ between the two groups (Table 3).

Results

Ventilation, patient temperature, length of stay on intensive care unit, day of discharge

Table 4 shows our study results in terms of need for postoperative ventilation, patient's core temperature, length of stay (LOS) on ICU, time to first defecation, administration of i.v. fluids, day of full oral food intake, and day of discharge. In the traditional group, 14/42 patients and 2/37 patients in the fast-track group needed postoperative assisted ventilation (33.3% vs. 5.4%; $p=0.011$). Temperature at the end of the operation did not differ significantly. Median LOS on ICU was shorter in the fast-track group, 20 vs. 41 h. During the postoperative period, i.v. fluids in the traditional group were administered for 5 days and in the fast-track group for 2.5 days (median); time to first postoperative defecation in both groups was 2 days and full enteral feeding was achieved after 7 days in the traditional and 5.5 days in the fast-track group. The median day of discharge was slightly earlier in the fast-track group (10 vs. 11 days, median).

Table 3 Overview over patient characteristics

	Traditional treatment ($n=42$)	Fast-track treatment ($n=37$)
Age [year]	68 [52–84]	67 [40–81]
Sex, male to female	39:3	34:3
AAA-diameter [cm]	5.5 [4.4–8.5]	5.5 [4.2–7.4]
Grafts used	Tube graft, $n=30$ Bifurcated graft, $n=12$	Tube graft, $n=32$ Bifurcated graft, $n=5$
Surgical approach	Retroperitoneal, $n=21$ Transperitoneal, $n=21$	Retroperitoneal, $n=24$ Transperitoneal, $n=13$
Clamping time [min]	57 [39–130]	60 [44–120]
ASA score		
ASA II	5	5
ASA III	34	32
ASA IV	3	0

Patients were comparable concerning age, sex, aneurysm diameter, grafts used, surgical approach, and ASA score. Values are given as median and range.
ASA American Society of Anesthesiologists, *AAA* abdominal aortic aneurysm

Table 4 Results in terms of need for postoperative ventilation, length of stay on intensive care unit (duration of administration of i.v. fluids, enteral feeding), and day of discharge

	Traditional treatment ($n=42$)	Fast-track treatment ($n=37$)	p value
Postoperative ventilation			
Yes	14	2	0.011
No	28	35	
Temperature at the end of operation [°C]	35.7 [34.4–37.1]	35.6 [35–36.6]	
LOS on ICU [h]	41 [12–192]	20 [14–336]	
Duration of i.v. fluid administration [days]	5 [3–12]	2.5 [1–40]	
Enteral feeding	7 [5–11]	5.5 [4–40]	
Day of discharge [days]	11 [8–24]	10 [8–49]	

Values are given as median and range.

Morbidity and mortality

Results of parameters screened in the postoperative course of the patients are listed in Table 5. We found cardiac complications in 4/42 (9.5%) patients in the traditional treatment group and in 2/37 (5.4%) in the fast-track treatment group. Infectious complications—urinary tract, i.v. line, and pneumonia—occurred in 4/42 patients in the traditional and in one patient in the fast-track group. With respect to gastrointestinal complications, we had five patients in the traditional and two patients in the fast-track group who showed signs of functional bowel obstruction. Acute renal failure with reduced urine output and elevated serum creatinine that needed medical intervention—fluid balance and i.v. diuretics—was documented in three and two patients, respectively. In summary, 15/42 patients in the traditional and 6/37 in the fast-track group experienced postoperative

Table 5 Postoperative complications and mortality in the postoperative course, in the conservative and the fast-track group. Different numbers result from patients with more than one complication

	Traditional treatment ($n=42$)	Fast-track treatment ($n=37$)	p value
Postoperative complications			
Myocardial ischemia	1	1	
Dysrhythmia	3	1	
Acute renal failure	3	2	
Pneumonia	1	0	
Functional bowel obstruction	5	2	
Urinary tract infection	2	1	
Intravenous line infection	1	0	
Patients	15/42 (35.7%)	6/37 (16.2%)	0.045
Death	0	0	

medical complications (35.7% vs. 16.2%; p=0.045). No death occurred during the observation period in both groups.

Discussion

Patients undergoing elective open infrarenal aortic repair experience complications in 20–59% [1, 4]. Median length of stay on ICU is 3.2 days. Mortality rates range from 1.2% in high-volume centers to 10.5% [2, 5]. After open repair, most common medical complications are myocardial ischemia, pneumonia, and acute renal failure depending on preexisting risk factors. Endovascular exclusion offers potential advantages over traditional open aneurysm repair in terms of operating time, blood loss, and shorter hospital stay, but late complications related to endovascular repair, such as late aneurysm rupture, graft migration, thrombosis, and endoleak, lead to similar morbidity and mortality rates [10, 11]. Hence, optimizing traditional open repair is desirable in order to reduce postoperative morbidity and mortality and to offer a new approach in the treatment of these patients. However, single interventions do not seem to be able to improve patients' outcomes after major vascular surgery. Therefore, multimodal therapeutic approaches—so-called fast-track programs—have been implemented to reduce morbidity and mortality after major surgical procedures [6]. As for elective open infrarenal aortic aneurysm repair, no fast-track protocol has been proposed and only a retrospective analysis of a patient care pathway exists [12]. Therefore, our pilot study aimed at proposing a "fast-track" patient care regimen for elective open aneurysm repair and evaluating this program in a prospective randomized controlled trial. For this purpose, we have modified and adopted various techniques from fast-track programs in other surgical specialties in order to develop a "fast-track" program for OR of abdominal aortic aneurysm (AAA).

We included patients with the indication for elective open infrarenal aortic aneurysm repair. Both groups were comparable with respect to sex, age, AAA diameter, ASA score, surgical procedures performed, and clamping time. Traditionally, preoperative fasting consists of a 6-h period of nothing by mouth, but it has been shown that preoperative carbohydrate drink may reduce postoperative endocrine responses [13]. As a consequence, patients in the fast-track group were allowed to drink clear drinks 2 h before operation. Another fact determining postoperative morbidity is intraoperative heat loss [14]. Hence, in our department, heat loss in patients undergoing major surgical procedures is usually prevented using external heating by air heaters on the operative table and the administration of warm i.v. fluids. In the fast-track protocol, warming of the OR to 22°C was additionally realized in order to avoid hypothermia in our patients. However, warming up the OR did not result in significant improvement of the patients' core temperature (35.7°C vs. 35.6°C).

Surgical procedures present stress for the patient and may induce organ dysfunction by release of various hormones (cortisol, catecholamines) and cytokines. After elective abdominal aortic aneurysm repair, 89% of the patients show signs of systemic inflammatory response syndrome and 3.8% develop multiple organ failure [15]. By blocking the afferent neural stimulus using epidural anesthesia, this surgical stress response can be diminished [16]. To date, regional anesthesia is regarded to be the ideal technique available to attenuate endocrine metabolic responses with extended effect on postoperative analgesia [17]. By this means, postoperative morbidity as compared with general anesthesia could be decreased [18]. We therefore used epidural analgesia in our fast-track regimen for both purposes—intraoperative stress reduction and postoperative pain control. The epidural catheter was inserted preoperatively and used postoperatively in a patient controlled manner (PCEA); it was removed as soon as pain relief could be achieved by i.v. opioids and NSAIDs alone, usually after 48 to 72 h.

After elective infrarenal aneurysm repair, approximately 25% of patients need postoperative mechanical ventilation [19]. In our series, "traditionally" treated patients needed postoperative mechanical ventilation in 33.3% which could be significantly decreased to 5.4% in the fast-track group; this effect can be explained by the reduced use of inhalative narcotics as intraoperative analgesia is realized by administration of sufentanil and ropivacaine via the epidural catheter. Additionally, the length of stay on ICU was shorter in the fast-track group, 20 vs. 41 h. According to the quality management report of the German Society of Vascular Surgery, 53% of patients require intensive care for more than 3 days [20]; there are attempts for a selective use of the intensive care unit, but later transfer to the ICU may be required and the median length of stay ranges between 3.2 and 4.2 days [1, 21].

Another factor that influences postoperative recovery after major surgical procedures is gastrointestinal function; after abdominal surgery, up to 20% require reinsertion of nasogastric tube and median time to first defecation is 3 days [22]. Restoration of gastrointestinal motility postoperatively is a multifactorial feature and attempts to enhance recovery of bowel function and adequate food intake are multifactorial as well, and postoperative patient management in this context is heterogenous and likewise controversial [23, 24]. However, in other surgical fields, early oral feeding, early patient mobilization, and the use of epidural anesthesia have been proposed in order to restore gastrointestinal function early [25, 26]. As a consequence, in our fast-track group, patients were allowed to drink clear fluids from the evening of the operation; after a median

time of 5.5 days, full enteral feeding was achieved; in the traditional group, this goal was realized after 7 days median. Vice versa, the need for postoperative administration of i.v. fluids was decreased to 2.5 days in the fast-track group, whereas patients in the traditional group needed i.v. fluids for 5 days.

As for the primary endpoint of our study—postoperative medical complications—we found a significant advantage for patients in the fast-track group, 35.7% vs. 16.2% (p= 0.045); the rates of cardiac, respiratory, renal, gastrointestinal, and infective complications were lower in the fast-track group.

After elective open repair of AAA, the median length of stay in US hospitals ranges from 3 to 8 days [2, 26]; in European countries, in-hospital stay is about 10 days [21]. The median length of stay in our series was 10 days in the fast-track group and 11 days in the traditional group. However, the primary concern of our study was not the reduction of in-hospital stay but the reduction of postoperative medical complications.

Conclusion

In summary, our study is—to our knowledge—the first prospective randomized trial to introduce and evaluate a fast-track recovery program for elective open infrarenal aortic aneurysm repair. It shows significant advantages in terms of need for postoperative mechanical ventilation and medical complications (cardiac, respiratory, renal, gastrointestinal, and infective). Implementation of this optimized perioperative patient management consisting of normal preoperative food intake, reduced preoperative fasting, and regional anesthetic techniques (epidural anesthesia) can significantly reduce the rate of medical complications in the postoperative course of these patients. These encouraging results should be confirmed by further multicentric studies.

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