ORIGINAL ARTICLE

EVAR FAST-TRACK, THE IMPLEMENTATION OF A SAFE AND COST-EFFECTIVE PROTOCOL

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Abstract

Introduction: *To evaluate and confirm the cost effectiveness and safety of a fast-track protocol discharge of patients after elective EVAR.*

Material and Methods: *A total of 83 patients admitted for elective EVAR procedure were collected in a database. The experimental group included 40 patients treated after the establishment of a fast-track EVAR protocol (from April 2020 to April 2023) in our hospital. The control group included 43 patients, standard admission, treated before 2020 (from January 2017 to December 2019). We collected data on the length of hospital stay and the costs derived from it, the need for re-intervention and the occurrence of major adverse events. We did a follow-up after 30 days and six months after the intervention.*

Results: *No differences were found in main demographic and clinical characteristics in both groups. There were no changes in clinical indication or surgical procedures between both groups. We observed a shorter hospital stay (2.3 vs 3.7 days p<0.001), less need for monitoring in the resuscitation unit (0.2 vs 1.1 days p<0.001) and lower rate of secondary intervention in the experimental group (fast-track group). In postoperative follow-up, the fast-track group also presented lower readmission rate for any reason (12.5% vs. 23.3%). The total cost per patient for the health system during the hospital admission was 1403.29 ± 820.3 euros in the experimental group and 3339.34 ± 2513.1 euros in the control group, resulting in a total saving per patient of 1936.05 euros (95% CI 2748.12 - 1123.97) in the fast-track group.*

Conclusions: *The implementation of a fast-track protocol for patients undergoing elective EVAR, results in a shorter hospital stay lowering perioperative costs, without increasing adverse events or readmission rate following discharge. Therefore, its practice should be considered as standard of care in patients admitted for EVAR procedure.*

Keywords: *Endovascular Aneurysm Repair (EVAR), fast-track protocol, hospital stay, safety, costs.*

INTRODUCTION

Infrarenal aortic aneurysms (IAA) still represent a health concern despite the decrease in its prevalence worldwide during recent decades[1]. IAA are known as silent killers since they often go unnoticed until they reach a critical stage. They might be asymptomatic until its rupture, a fatal condition that has a huge death rate. That is why early detection for proper intervention is crucial. The prevalence of IAA increases with age, sex (male), smoking condition and family history of cardiovascular disease[2]. The incidence changes between different populations, but has generally increased the past decades because of the aging of the global population and the progress in medicine (improvement in detection methods and treatment skills).

Endovascular Aneurysm Repair (EVAR) has emerged as an innovative alternative becoming an increasingly popular treatment choice in the management of IAA. EVAR is a minimally invasive procedure that involves deploying a stent graft through eco-guided punction of both groins[3]. Compared to traditional open repair of IAA, this less invasive way of treatment has demonstrated to be a safe and effective alternative. This method offers a reduced mortality and lower complication rates because avoids large incisions and the need of an aortic clamping; faster recovery and shorter hospital stay, reducing costs; and an increased accessibility because it is a therapy that suits for a broader range of patients, including those that are not candidates for open surgery (due to age or underlaying health conditions)[1].

Over the past several years, numerous centres have implemented the use of early-discharge strategies in patients treated by EVAR, this is known as enhanced recovery after surgery (ERAS) in numerous medical disciplines[4]. In recent years, some studies have been published evaluating different fast-track protocols in this type of interventions[5,6,7,8]. In general, these protocols consist of using percutaneous closure devices avoiding incisional groins as well as avoiding general anaesthesia or skipping an Intensive Care Unit (ICU) night stay by making a faster post procedure recovery to facilitate and early a discharge.

The objective of introducing a fast-track protocol is mainly to reduce the costs derived from hospitalisation, improving EVAR´s efficiency. All of our EVAR procedures underwent general anaesthesia and we always used percutaneous closure devices (mainly Perclose). The main factor that changed since we started in April 2020 the short-stay protocol was to bypass the ICU monitoring stay. After five hours in the postoperative recovery room, the patient is discharged to the hospitalisation floor. Once there, the urinary catheter is removed and oral tolerance is started. The second post operatory day, we perform a control analytic, the patient gets up to shower and is discharged after lunch if everything is fine. With this protocol, an ICU stay is eluded, avoiding unnecessary costs derived from it.

With this study, we aim to measure the cost effectiveness of a fast-track protocol, among the patients that underwent a similar EVAR technique to treat an IAA between 2017- 2019 (pre pandemic years) and 2020- 2023 (pandemic and post pandemic years).

MATERIAL AND METHODS

We performed a retrospective analysis of collected data from the patients treated by EVAR in our centre. Our study included a total of 83 patients that were eligible to perform a standard EVAR procedure using bilateral percutaneous access with 14 to 18 Fr stent grafts (including Gore, Cook, Minos, Endologix, Medtronic, Bolton, Jotec and Cordis). These endoprothesis share common design principles, including a metallic stent framework (typically nitinol) covered with a durable graft material such as ePTFE or Dacron. They are delivered through catheter-based systems via femoral access and are available in different configurations to adapt to variable anatomies. The chosen to treat our patients was the bifurcated configuration composed by two or three components including main body stent graft and iliac extensions. Access vessel were common femoral arteries with diameters ranging from 7 to 11 milimeters.

All of the patients treated were infrarrenal aneurysms (ICD-10 codes 171.3 and 171.4) and complex juxtarrenal or suprarrenal cases were excluded. We also excluded patients with associated treating vascular comorbidity that could impede faster recovery. Regarding the anatomical characteristics of the treated aneurysms, all cases were managed exclusively by EVAR, with primary sealing in common iliac arteries (occasionally in the external iliac). Cases with hostile necks requiring endoanchors or those with associated iliac aneurysmal disease were also excluded.

Experimental group included a total of 40 patients that underwent an EVAR procedure after the establishment of the fast-track EVAR protocol in our department (from April 2020 to April 2023). Of note, few cases are reported in this period of time because of the COVID pandemics. All of the standard EVAR procedures executed in this period of time, underwent this protocol without exception. Patients underwent general anaesthesia and a percutaneous access was performed. After a brief recovery period of a few hours, patients were transferred to hospital ward and discharged 24 hours postoperatively, with follow-up ultrasound confirming the absence of complications at the puncture sites.

Control group included 43 patients that underwent EVAR cases treated prior to the establishment of this protocol (from January 2017 to December 2019). These group of patients, also underwent general anaesthesia and percutaneous access was performed, but they spent one night at the ICU for monitoring after intervention.

We collected data on the length of hospital stay and the costs derived from it, the need of re-intervention and the occurrence of major adverse events (MAE, including here major cardiovascular complications such as myocardial infarction, ictus, acute limb or gastrointestinal ischemia or acute renal failure) or death. We did a follow-up after 30 days and 6 months after primary intervention to see and compare the need of re-intervention, the presence of major adverse effects after discharge between both groups.

Demographic variables included age, gender, diabetes mellitus, dyslipidemia, arterial hypertension, cardiopathy, chronic obstruction pulmonary disease (COPD), renal insufficiency, peripheral arterial disease (PAD).

The main inclusion criteria for patients treated by EVAR, under fast-track protocol or not, were: male or female with IAA of > 5 cm diameter or increased > 0.5 cm diameter in last half year with suitable anatomy for standard infrarrenal EVAR and according to Instructions For Use (IFU) of each device in a scheduled intervention. Main exclusion criteria for both groups were: ruptured AAA, prior endovascular iliac or aortic repair, isolated iliac aneurysm, the need of complex repair (with fenestrated, inner/outer branch or scallop endoprosthesis), an associated treating vascular comorbidity or non-scheduled treatment (urgent treatment). All patients were collected in a database that safeguard ethical standards but no review board was approved because of the retrospective character of the study.

Statistical Analysis

We used the SPSS 25 program (IBM Corporation version 25.0, Armonk, NY) for data processing. Continuous variables are shown with mean $\pm$ standard deviation

Table 1 **Description of the basal conditions of the 83 patients included in the study, comparing both groups and with a p value of > 0.05. COPD (Chronic Obstructive Pulmonary Disease), PAD (Peripheral Arterial Disease)**

	FAST-TRACK GROUP (n=40)	CONTROL GROUP (n=43)	p
Age	75.6 ± 7.3	75.9 ± 6.8	0.854
Male	37 (92.5%)	42 (97.7%)	0.348
Women	3 (7.5%)	1 (2.3%)	0.348
Diabetes Mellitus	4 (10 %)	12 (27.9%)	0.052
Dyslipidemia	22 (55 %)	22 (51.2%)	0.726
Arterial Hypertension	32 (80 %)	28 (65.1%)	0.130
Cardiopathy	16 (40 %)	13 (30.2%)	0.351
COPD	5 (12.5 %)	6 (14 %)	0.845
Renal Insufficiency	6 (15%)	3 (7 %)	0.302
PAD	5 (12.5 %)	4 (9.3 %)	0.732
Maximum sac diameter	58.54 ± 7.4	59.2± 11	0.741

Continuous variables mean +/- standard deviation, and categorical variables %

Table 2 **Comparative table of total ICU and hospitalization days and reintervention, MAE, death and readmission after discharge at 30 days and readmission before 6 months. ICU (Intensive Care Unit), MAE (Major Adverse Events)**

	FAST-TRACK GROUP (n=40)	CONTROL GROUP (n=43)	p
ICU days	0.18 ± 0.39	1.14 ± 0.83	< 0.001
Total hospitalization days	2.28 ± 0.91	3.70 ± 2.96	0.004
Reintervention	0	1 (2.3%)	0.338
MAE	0	1 (2.3%)	0.338
Exitus	0	0	-
Reintervention < 30 days	1 (2.9%)	2 (4.6%)	0.297
MAE < 30 days	0	0	-
Death < 30 days	1 (2.9%)	0	0.323
Readmission before 6 months	5 (12.5%)	10 (23.3%)	0.204
Total readmission days	0.65 ± 2.08	1.95 ± 5.21	0.135

Table 3 **Total cost per admission per patient in each group**

	FAST-TRACK GROUP (n=40)	CONTROL GROUP (n=43)	p
During primary admission	1403.29 ± 820.3	3339.34 ± 2513.1	< 0.001
Postdischarge (at 6 months)	2161.81 ± 2274.2	4864.55 ± 4343.8	0.001

(SD) and percentage of patients was used for categorical variables. The cost allocation was carried out according to DOGA 2014 [9], the official document that stablishes medical costs for public hospitals in Galicia. The differences between groups were tested by Fisher exact or Chi-square tests for categorical variables. Continuous variables were compared under Student's T-test. A significance level of 0.05 was used for all analyses.

RESULTS

Patient characteristics

We collected data about age, sex, diabetes mellitus, dyslipidemia, arterial hypertension, cardiopathy, COPD, renal insufficiency, PAD and medium of maximum sac diameter in each study groups. Table 1 shows that no statistically differences between patient's main characteristics in both groups were found.

Hospitalization days and adverse events

Total ICU and hospitalisation days in each group are collected in table 2, which shows a statistically difference between both of them. The mean ICU days for the fast-track group was 0.18 ± 0.4 days versus 1.14 ± 0.8 days (p value < 0.001) in the control group. There is also a statistically difference between total hospitalisation days (2.28 ± 0.91 in the fast-track group vs 3.7 ± 2.96 in the control group, p value 0.004). During primary admission, there were no differences found between groups in terms of re-intervention, MAE or death. After discharge, during the follow up (at 30-day and six month), there were no differences found between groups in re-intervention, MAE, death or hospital readmissions.

In the fast-track group there were no patients that experienced re-interventions or MAE during primary admission. In the control group, one patient needed a re-intervention due to a type Ib endoleak that was treated by implantation of a left iliac branch device. Another patient of this group experienced an acute renal failure after procedure that required permanent hemodialysis. No death was reported in any group.

During 30 day follow up, there was one re-intervention in the fast-track group due to an acute thrombosis of an iliac extension that was treated by realigning the iliac axis by implantation of a Viabahn. There were two re-interventions in the no fast-track group, one was an inguinal abscess drainage because of infection of the puncture inguinal access and the other one was the creation of a radio-cephalic fistula in the patient that had renal failure and needed chronical hemodialysis. There was one death in the early discharge group due to an acute myocardial infarction in postoperatory day 24th. No other major adverse events were reported during the first 30 postoperatory day.

All cause hospital readmissions before six months were five (12.5%) in fast-track group. Causes were acute myocardial infarction that needed myocardial revascularization, a renal tumor that was treated by nephrectomy, a distal bypass because of a popliteal aneurysm, hemoptysis in a patient that ended up with a pulmonary neoplasia diagnosis and an upper gastrointestinal bleeding. In the no fast-track group, there were ten readmissions (23.3%) and the most common causes were urological problems, exacerbated chronic renal failure and cardiovascular complications. None of the hospital readmissions were related to the EVAR procedure.

The median readmission hospitalisation was 0.65 ± 2.1 days in fast-track group vs 1.95 ± 5.2 in control group (p value 0.135) with no significant difference between them.

Perioperative health costs

The cost allocation of hospitalisation was made following the Diario Oficial de Galicia (DOGA), the official publication that stablishes the rates of health services provided in Hospitals dependent on the Galician Health Service and in public health foundations. The hospitalisation stay ward was 528.95 euros per day and the ICU night stay was 1142.47 euros. The vascular endograft implantation had a cost of 3507.59 per patient. We also calculated re-intervention costs, readmission costs and other necessary procedures during admission or readmission according to the prices established by DOGA for each procedure. Under this premise, we could calculate the total cost in each patient during primary admission and follow up.

Table 3, summarizes the total cost per patient in euros during primary admission and at six month follow up. Table shows the total cost per admission per patient during primary admission, which was 1403.29 ± 820.3 euros in the fast-track group and 3339.34 ± 2513 euros in the no fast-track group, throwing a statically difference of 1936.05 euros (95% CI 2748.12 - 1123.97) between them. Figure 1 is a box plot that illustrates these results. Total costs after a six month follow up were 2161.81 ± 2274.2 in fast-track group and 4864.55 ± 4343.2 in EVAR standard group. The costs during follow up were calculated by adding to the total cost of primary admission the cost of each re-intervention or readmission in both study groups according to the DOGA rates of each procedure (9). The difference of costs between groups after six months was also statistically significant resulting in 2702 euros (95% CI 4208.13 – 1197.35) saving in the early discharge group. Figure 2 is a box plot that illustrates these results.

DISCUSSION

Since EVAR treatment has become increasingly popular for non-invasive, rapid and effective management among today's vascular surgeons, and its technique is becoming more refined, more studies analysing the technique are emerging. This past decades, literature reported increasingly number of studies about safeness of fast-track protocols[10], but there are few about effectiveness. Preece R et al [11] conclude in their article that include nine relevant studies in short-stay EVAR that this protocol can be

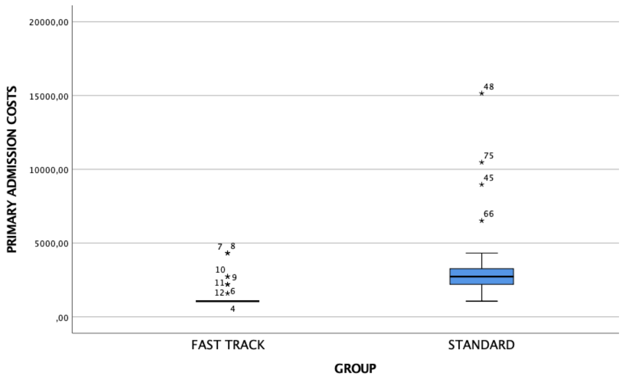

Figure 1 *Box plot demonstrating the total cost per admission per patient during primary admission.*

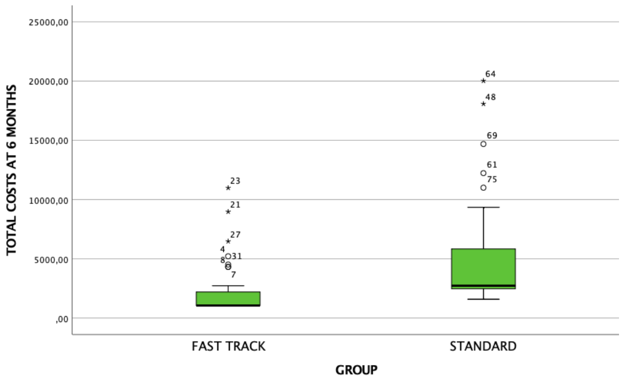

Figure 2 *Box plot demonstrating total cost of follow-up after 6 months.*

safe and efficient in well selected patients. It is important to demonstrate the safety of a procedure, but it is also important to look for financial implications. Implementation of efficient procedures will also allow treating more patients.

Heath economy is an important feature that cannot be analysed apart from clinical success. Cost effectiveness in surgical procedures such as EVAR is crucial in health care resource allocation and patient care optimization. In an era of resource constraints and increasing demand for quality health care services, understanding the economic dimensions of surgical interventions is indispensable for achieving sustainable and equitable health care delivery.

In this study, it was expected to find substantial savings in terms of hospitalisation costs per patient in the short-stay group, because of the skipping night stay at ICU with the fast-track protocol, allowing a faster discharge of the patients. Total operative and hospitalisation care costs were 1936 euros lower in fast-track group of patients. But lowering hospitalisation costs would not be relevant if during the follow up these patients would have more complications or higher readmission rates. Interestingly, our studied showed that post-discharge outcomes were similar in both groups in terms of MAE, re-interventions and all cause hospital readmissions. Regarding the comparison of costs, only their difference in terms of time/days of hospital stay has been taken into account, differentiating the ICU and standard hospitalisation days, assuming that costs derived from each performed EVAR were the same.

A substantial saving of money is seen if we only analyse the hospitalisation days at primary admission. The costs in the fast-track group would be 1403.29 euros per patient and the costs in the EVAR standard group would be 3339.34 euros, more than twice the price in the early-dismissal group.

In terms of costs, it is also remarkable the fact that the no fast-track group had more readmissions that required many procedures and more hospitalisation days than the other group, something that turned out in an important increasing average expense in this group. Although we did not investigate furthermore, this could be explained because of the longer hospital stay at primary admission in this group of patients, arising the probability of complications derived from it.

There is scarce on data about cost savings in fast-track protocol studies in EVAR treatment. Researching, we found two studies investigating financial implication of early discharge in EVAR. Moscato et al [6], reported 2400-dollar savings in patients with same day discharge after EVAR comparing to those who required monitoring after procedure. Al-Zuhir et al [5], found 2500-dollar savings in patients with next day discharge after EVAR procedure. The results in our study (1936-euros saving) were in line with these previous studies. Nevertheless, these studies did not have a post discharge follow up of the patients.

This is further shown by Z. Krajcer et al [8], in their study about perioperative health costs in patients undergoing a fast track versus standard EVAR procedure including more among 1000 matched patients. They reported a 2980-dollar saving in the fast-track EVAR showing that post discharge outcomes also favored this group (in terms MAE rates and all cause readmission). Even though, this study was performed in the United States, a country with different reimbursement requires, and in which most procedures performed at private hospitals, something to be careful about when comparing and drawing conclusions.

An important thing to focus on in this analysis is that, as mentioned before, despite the money savings per patient with fast-track protocols, the safeness procedure is guaranteed. Z.Krajcer et al [8], demonstrated cost savings in fast-track EVAR procedures in the US, as well as safety (achieving limited readmission and re-intervention rates), but no other studies were found about it. In our study, an important source of cost increase was due to the greater number of readmissions in no fast-track group, something which meant savings in the other group that had less readmission rates.

LIMITATIONS

There are several limitations in our study. First of all, we performed a retrospective analysis that included only 83 patients, a low number that limits and makes difficult the generalizability of the outcomes. The number of patients included was particularly low because, at the time we started the fast-track protocol, we were still affected by the COVID-19 pandemic and did not have full-time access to operating rooms. In this context, a potential selection bias toward less clinically complex patients treated during the pandemic cannot be excluded. Additionally, our institution manages a considerable number of complex EVAR cases, which were not the focus of this study.

Regardless the results of our work, there would be necessary to make a longer follow up to see if similar rates in complications remains in time.

Regarding cost imputation, we would also like to mention several limitations of our study. Firstly, the document used for cost allocation (DOGA 2014), is probably outdated at this time, because after almost ten years, costs of each procedure, interventions or hospital stay are probably higher. On the other hand, there are other reasons of health care costs that have not been studied, such as number of consultations required, prescribed medical treatment or sick leave days per patient. Although, by protocol, there were not differences in the groups included in our study.

CONCLUSIONS

The implementation of a fast-track protocol for patients undergoing EVAR, results in a shorter hospital stay, lowering perioperative costs, but has also demonstrate to be a safe option, without increasing adverse events or readmission rate following discharge. Therefore, its practice in well selected patients should be considered to optimize the hospital costs derived from the EVAR procedure as standard of care.

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