

# Incidence of endoleaks in patients with infrarenal abdominal aortic aneurysms treated on with the endovascular technique

Incidencia de endofugas en pacientes con aneurismas de aorta abdominal infrarrenal intervenidos con técnica endovascular

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## Summary

**Introduction:** Endoleaks are the most common complication of endovascular treatment of abdominal and thoracic aortic aneurysms. The objective of this study is to describe the frequency of endoleaks in patients with infrarenal aortic aneurysms treated with endovascular techniques.

**Methodology:** Retrospective cohort study that included patients from September 1, 2013, to March 1, 2021, with infrarenal aneurysms treated with endovascular therapy at the FOSCAL and FOSCAL international clinics. Demographic data, history, morphological characteristics of the aneurysm neck and sac, type of prosthesis used, presence, and type of endoleak were included. A univariate descriptive analysis was performed. Confidence intervals were reported at 95%. **Results:** 99 patients were included, the mean age was 74.37 years, the mean neck length was 29.47 mm, 90.24% had a favorable length (>15 mm); The mean angle was 44.57, 67.86% had a favorable angle (<60°). 28.28% of the patients presented endoleaks, the frequency of type Ia endoleaks was 7.07%, type Ib endoleaks 8.08%, type II 18.37%, type IIIa, and IIIb endoleaks 1, 01%. There were no type IV or type V endoleaks. **Conclusions:** The frequency of presentation of endoleaks was 28.28%; the most frequent endoleak is type II 18.37%, slightly lower than that reported in the literature.

## Resumen

**Introducción:** Las endofugas son la complicación más frecuente de los tratamientos endovasculares de aneurismas de aorta abdominal y torácica. El objetivo de este estudio es describir la frecuencia de endofugas en pacientes con aneurismas de aorta infrarrenal tratados con técnicas endovasculares.

**Metodología:** Estudio de cohorte retrospectivo en el que se incluyeron pacientes con aneurismas infrarrenales tratados con terapia endovascular en dos instituciones de alta complejidad entre el 1 de septiembre de 2013 y el 1 de marzo de 2021. Se incluyeron datos demográficos, antecedentes, características morfológicas del cuello y saco del aneurisma, tipo de prótesis utilizada, presencia y tipo de endofuga. Se realizó un análisis descriptivo univariado. Los intervalos de confianza se describieron con un 95 %. **Resultados:** Se incluyeron 99 pacientes, la media de edad fue 74,37 años, la media de la longitud del cuello fue de 29,47 mm, el 90,24 % tuvieron una longitud favorable (> 15 mm). La media del ángulo fue de 44,57°, el 67,86 % tenía un ángulo favorable (< 60°). El 28,28 % de los pacientes presentaron endofugas, la frecuencia de las endofugas tipo Ia fue de 7,07 %, las de tipo Ib 8,08 %, las de tipo II 18,37 %, las de tipo IIIa y IIIb 1,01 %. No se presentaron endofugas tipo IV ni V. **Conclusiones:** La frecuencia de presentación de endofugas fue del 28,28 %; la endofuga más frecuente es la de tipo II 18,37 %, ligeramente inferior a lo descrito en la literatura.

## 1. Introduction

Endovascular repair is the treatment of choice in most cases of abdominal and thoracic aortic aneurysms; however, endoleaks are the most frequent complications (1, 2). Variable percentages of endoleaks of 20-50% have been reported (3).

Endoleaks are defined as persistent blood flow in the aneurysmal sac after endovascular treatment; this is due to the fact that there is no complete exclusion of the aneurysm (4). These are traditionally classified into five types according to their origin and location Type I endoleaks, which represent 12% of cases, are those in which there is not an adequate coupling of the prosthesis.

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sis to the walls of the proximal aorta (Ia) (Figure 1) and/or distal iliac arteries (Ib) (Figure 2), often due to calcifications, thrombi, tortuosity, angulation of the aneurysmal neck and/or an inappropriate device (5). They can be observed immediately after stent deployment or later, and require reintervention (6, 7). Type II endoleaks are the most common (Figure 3), their origin and management is still a controversial issue (3, 8). Among the possible theories of their genesis is the persistent pressurization of the aneurysm sac by retrograde flow of the vessels of the collateral aortic branches; generally, the inferior mesenteric artery or one or more lumbar arteries are involved, although the middle sacral artery or accessory renal arteries may also be involved (9, 10), and they represent 76% of the types of endoleaks. Type III endoleaks are due to defects and/or fractures of the material of the stent components (IIIb) or uncoupling of the stent components (IIIa), and account for 3% of the cases (Figure 4). Type IV endoleaks are due to device porosity; and type V endoleaks are generated by endotension -expansion of the aneurysm sac without a demonstrable leak- and carry a long-term risk of rupture of the sac (3).

The relationship between aneurysm structural factors and endoleaks after treatment has not been well studied. It has been found that patients with high thrombus burden (> 50%) have lower inferior mesenteric artery patency, compared to those with lower percentages of thrombus, which is associated with greater regression of the aneurysmal sac and less presence of type II endoleaks (11).

The aim of this study is to describe the frequency of endoleaks in patients with infrarenal aortic aneurysms treated with endovascular techniques in the institution to which the authors belong.

## 2. Methodology

This is a retrospective cohort study, in which all patients diagnosed with infrarenal aortic aneurysms treated endovascularly between September 1, 2013 and March 1, 2021 were included. This study was approved by the institutional ethics committee and, due to its nature, informed consent was not required. Information was taken from an anonymized institutional database.

Demographic data on age and sex, and pathological antecedents of the patients such as smoking, arterial hypertension and previous anticoagulation were included. The variables related to the characteristics of the aneurysm neck were: length, diameter, shape, calcification, thrombus and neck angulation; those measuring less than 60° were considered favorable angles and those measuring 15 mm or more were considered favorable lengths. Regarding the variables associated with the aneurysm sac, the anteroposterior diameter, transverse diameter and mural thrombus were included. Calcification of iliac arteries, involvement of common iliac arteries, thrombus in iliac arteries, hypogastric artery aneurysm were evaluated. The type of stent used and the need for embolization of the hypogastric arteries were also included. Regarding the variables related to endoleaks, the following were included: presence of endoleak, type of endoleak and time in which the endoleak appeared in days.

### 2.1 Technique of endovascular repair of infrarenal aortic aneurysm and patient follow-up

The procedures were performed in angiography rooms with equipment with digital subtraction and 3D technology. All patients were under general anesthesia; after asepsis and antisepsis, the femoral arteries were

accessed by percutaneous endovascular puncture technique, which was performed under ultrasound control.

Subsequently, the 8Fr introducer kit was advanced through each femoral access and a pigtail catheter was introduced to perform abdominal and lower limb aortograms. Next, a standard cobra catheter was advanced through a femoral access and the hydrophilic guidewire was exchanged for a support guidewire (Lunderquist). Then, the 8Fr introducer was removed and the main body of the stent was introduced through a femoral access and released at the inferior border of the lowest renal artery. Afterwards, the extensions were connected to each of the primitive iliac arteries; in some cases it was necessary to embolize the hypogastric arteries (with coils) and perform extensions of the external iliac arteries. Once the connections were made, angioplasties were performed, specifically at the connection points and proximal and distal to the stent. Angiographic control was performed to verify adequate exclusion of the aneurysm and to rule out endoleaks which, if necessary, were treated immediately. Finally, the systems were removed and the femoral accesses were closed with percutaneous endovascular sutures, placed at the beginning of the procedure.

During the endovascular procedure, patients were anticoagulated with 80-100 IU/kg of unfractionated heparin until an activated clotting time (ACT) greater than 220 was achieved.

Upon patient discharge, follow-ups were done at eight days to remove the suture material from the skin of the femoral access, at three months with Angio-CT with contrast medium, if renal function allowed it -through institutional protocol- and at one year with duplex or Angio-CT depending on renal function and the findings of the first Angio-CT. Patients continue to be monitored every year with either of the two aforementioned methods, for up to five years. If any type of endoleak is detected, it will be evaluated and depending on the type, immediate treatment or follow-up will be given. In the case of types I and III, treatment will be immediate; in type II, follow-up will be done after one year and if an increase in the diameters of the sac greater than 0.5 cm is shown, treatment will be performed; it can be percutaneous or transarterial, the latter depending on a good identification of the vessel related to the type II endoleak. It should be noted that more than 30% of type II endoleaks resolve spontaneously (12).

### 2.2. Institutional protocol for abdominal aortic CT angiography

The patient is placed in the supine decubitus position, entering cephalocaudally, starting the acquisition at the level of the diaphragm. First a simple phase is performed and then the Ultravist® contrast medium, 300 mg/mL (Bayer Healthcare) (80-90 mL/kg, maximum 90 mL) is injected through an 18-20 gauge cannula, with an injector pump at a flow rate of 5-6 mL/sec. Once the ROI (region of interest) reaches a density of 180 HU in the abdominal aorta, images are obtained with 0.5 mm thickness with 0.3 mm reconstruction interval using a multi-slice tomograph with 320 detector lines (Toshiba), to obtain the arterial phase from the diaphragm to the pubic symphysis. After 60 seconds, the venous phase is taken starting at the pubic symphysis up to the diaphragm. Finally, images are obtained with 3 mm axial, coronal and sagittal slices and the three-dimensional reconstruction of the abdominal aorta is performed.

In patients with borderline renal function and with indication of Angio-CT for its intrinsic advantages of spatial and image resolution, through an access in the radial artery, leaving the tip of the catheter in the intrathoracic aorta, which allows the use of contrast medium doses of 5-10%, obtaining images of very high quality for this purpose.

### 3. Statistical analysis plan

Univariate descriptive analysis was performed for each of the variables evaluated, as well as a description in mean or median for continuous variables and in proportions for categorical and nominal variables. Confidence intervals are described at 95 %.

### 4. Results

From September 1, 2013 to March 1, 2021, 125 patients with infrarenal aortic aneurysms were treated. Twenty-six patients were excluded due to lack of follow-up data, procedure and/or aneurysm characteristics. Finally, 99 patients with a diagnosis of infrarenal aneurysm managed with endovascular treatment were included; of these, in 18 patients the information on the morphology of the aneurysm neck was not available and 15 did not have the neck angulation data.

Of the 99 patients, 79.80% were men. The mean age was 74.37, the minimum age was 59 years and the maximum age was 92 years. The most frequent antecedent was arterial hypertension in 77.78 % (Table 1).

**Table 1. Description of demographic variables and antecedents**

Variable	n (%)	(95 % CI)
Sex (%)		
Male	79 (79.80)	(70.56 - 86.68)
Female	20 (20.20)	(13.31 - 29.43)
Age *	74.37 (7.58)	.
Antecedents		
Hypertension	77 (77.78)	(68.36 - 85.00)
Previous smoking	35 (35.35)	(26.44 - 45.40)
Active smoking	27 (27.27)	(19.29 - 37.03)
Anticoagulation	7 (7.07)	(3.36 - 14.26)

\*(mean [SD]).

#### 4.1. Aneurysm neck characteristics

Of the patients analyzed, three had no aneurysm neck length. The mean neck length was 29.47 mm, the minimum was 8 mm and the maximum was 70 mm. The mean neck diameter was 29 mm, the minimum 16 mm and the maximum 33 mm. The most common neck shape was straight in 69.51 % of the patients (Table 2).

**Table 2. Anatomical description of the neck of the aneurysm**

Cuello del aneurisma	n (%)	(IC 95 %)
Calcifications	10 (12.20)	(6.60 - 21.44)
Thrombus	6 (7.32)	(3.26 - 15.57)
Neck shape		
Straight	57 (69.51)	(58.51 - 78.65)
Inverted conical	23 (28.05)	(19.24 - 38.93)
Tapered	2 (2.44)	(0.59 - 9.48)
Neck length*	29.47 mm (12.93)	.
Neck diameter*	20 mm (3.05)	.
Neck angle*	44.57 (25.15)	.
Favorable angle (< 60°)	57 (67.86)	(56.94 - 77.11)
Favorable length (> 15 mm)	74 (90.24)	(81.45 - 95.11)

\*(media [DE]).

Of the treated patients, the mean anteroposterior diameter of the sac was 59.60 mm, the smallest diameter was 50 mm and the largest was 130 mm. The mean transverse diameter was 60.18 mm, the smallest transverse diameter was 50 mm and the largest was 139 mm. Of the patients evaluated, 33.33% were associated with aneurysm of the primitive iliac arteries, which can be uni or bilateral. Of these, 77.78% were found to have mural thrombus. An aneurysm in the hypogastric artery was found in 7.07%. In 66.67% of patients calcification was found in the primitive iliac arteries. In the study, 30.30% of patients required embolization of the hypogastric artery (Table 3).

**Table 3. Anatomical description of the aneurysm sac, iliac arteries and aneurysm treatment**

Aneurysm sac	n (%)	(95 % CI)
Ruptured	8 (8.08)	(4.04 - 15.50)
Anteroposterior diameter*	59.60 mm (13.84)	.
Transverse diameter*	60.18 mm (13.39)	.
Presence of thrombus	77 (77.78)	(68.36 - 85.00)
Involvement of common iliac and hypogastric arteries		
Thrombus in iliac arteries	19 (19.19)	(12.49 - 28.32)
Calcifications in iliac arteries	66 (66.67)	(56.65 - 75.36)
Hypogastric aneurysm	7 (7.07)	(3.36 - 14.26)
Common iliac aneurysm	33 (33.33)	(24.63 - 43.34)
Type of stent used		
1. Medtronic	41 (41.41)	(31.99 - 51.50)
2. Cook	19 (19.19)	(12.49 - 28.32)
3. Gore	17 (17.17)	(10.86 - 26.07)
4. Incraft	6 (6.06)	(2.70 - 13.00)
5. Aorfix	7 (7.07)	(3.36 - 14.26)
6. Anaconda	4 (4.04)	(1.49 - 10.43)
7. Endologix	3 (3.03)	(0.96 - 9.14)
8. Nelix	1 (1.01)	(0.13 - 7.04)
9. Excluder	1 (1.01)	(0.13 - 7.04)
Hypogastric embolization	30 (30.30)	(21.94 - 40.21)

\*(media [DE]).



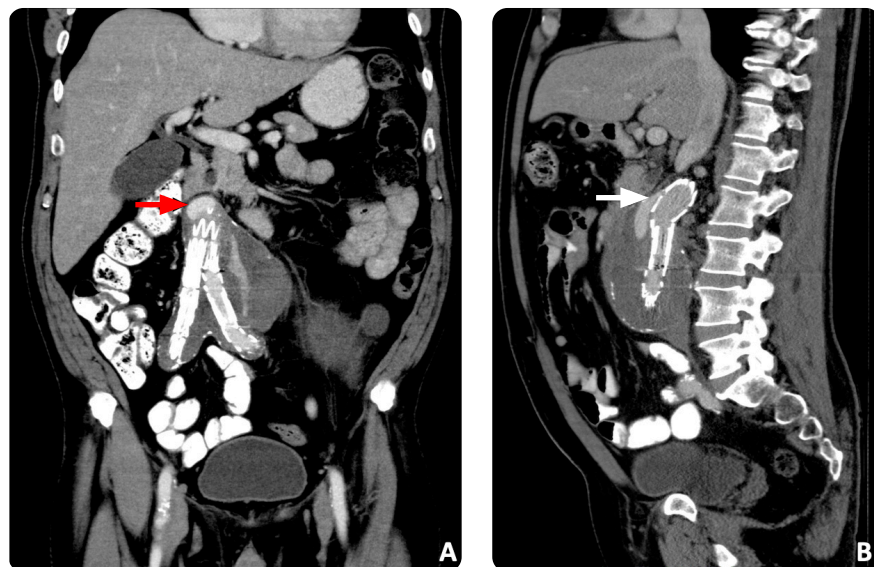


Figure 1. Abdominal CT with contrast medium: a) coronal section and b) sagittal section. The arrows indicate the leakage of contrast material between the aortic wall and the prosthesis, corresponding to a type Ia endoleak.

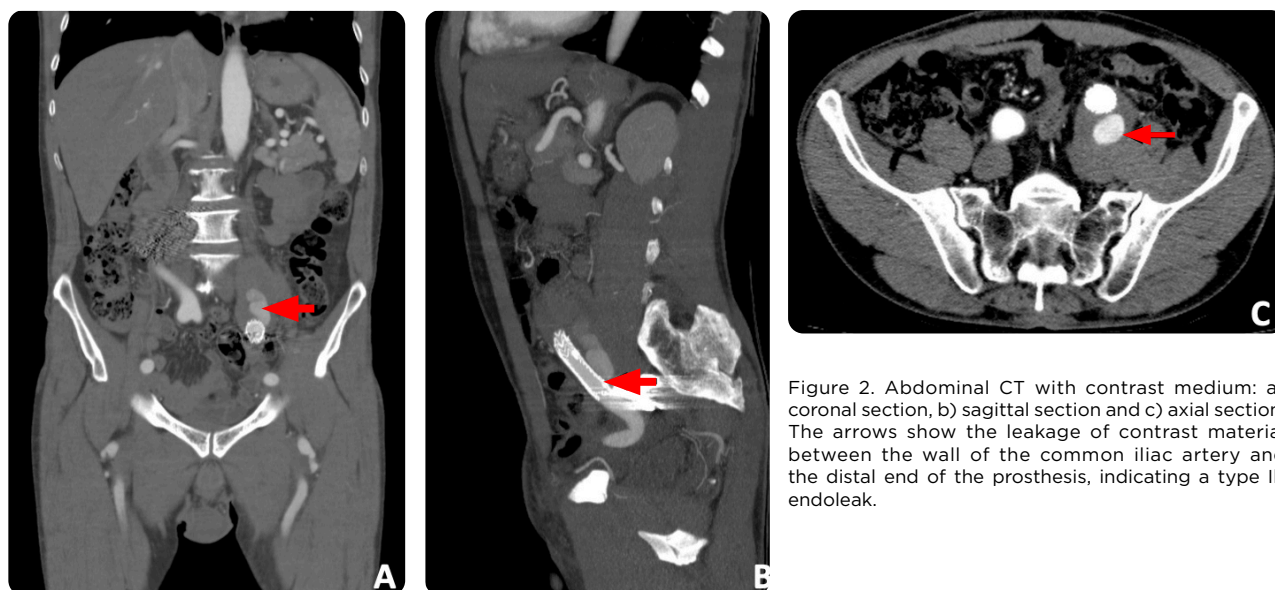


Figure 2. Abdominal CT with contrast medium: a) coronal section, b) sagittal section and c) axial section. The arrows show the leakage of contrast material between the wall of the common iliac artery and the distal end of the prosthesis, indicating a type Ib endoleak.

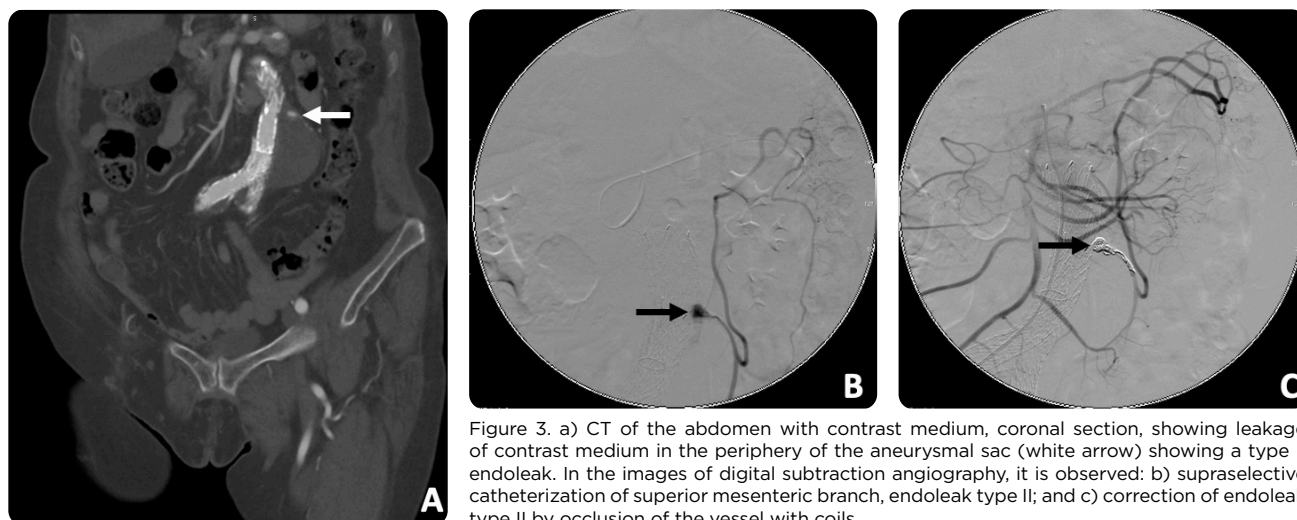


Figure 3. a) CT of the abdomen with contrast medium, coronal section, showing leakage of contrast medium in the periphery of the aneurysmal sac (white arrow) showing a type II endoleak. In the images of digital subtraction angiography, it is observed: b) supraselective catheterization of superior mesenteric branch, endoleak type II; and c) correction of endoleak type II by occlusion of the vessel with coils.

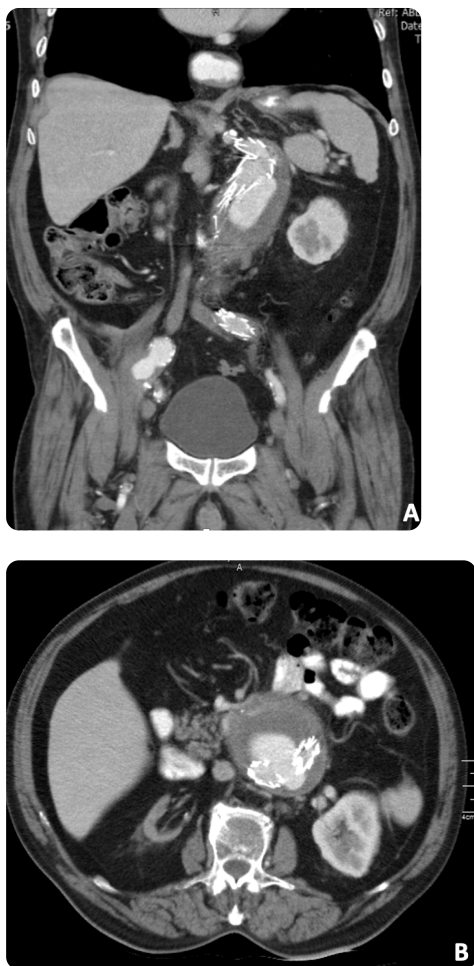


Figure 4. Abdominal CT with contrast medium: a) coronal section and b) axial section. There is evidence of contrast medium leakage adjacent to the prosthesis due to fracture of the stent material, corresponding to a type III endoleak.

Endoleaks were present in 28.28% of patients. The most frequently detected endoleak was type II, with 66.67 % of all endoleaks; no endoleaks of types IV or V were found. The time of presentation for each type of endoleak was calculated; however, the data were not available for all patients. The mean time to presentation for type Ib endoleak was 335 days, for type II it was 197 days, for type IIIa it was 3 days and the mean for type IIIb was 861 days (Table 4).

Of the 99 patients analyzed, four died (4.04%) due to complications related to the endovascular procedure. The first patient suffered thrombosis of the mesenteric artery, the second died from complications related to hypovolemic shock secondary to femoral artery injury. The third patient had spinal shock secondary to embolization of the hypogastric artery and the last patient, with a history of arterial hypertension and chronic renal insufficiency, died of distributive shock in the postoperative period. Additionally, two patients admitted with ruptured aneurysms died from hypovolemic shock in the perioperative period (2.02%).

No patient had endoleak rupture during follow-up. Only those who showed an increase in the diameter of the sac were treated; those who did not show an increase were not treated and most of them disappeared on their own over time. However, these variables were not included in the database, since the previous registry was not available.

Table 4. Presence of endoleaks and complications

Variable	n (%)	(95 % CI)
Presence of endoleak	28 (28.28)	(20.17 - 38.09)
Number of endoleaks presented		
1	19 (19.39)	(12.62 - 28.59)
2	8 (8.16)	(4.08 - 15.65)
Type Ia	7 (7.07)	(3.36 - 14.26)
Type Ib	8 (8.08)	(4.04 - 15.50)
Type II	18 (18.37)	(11.79 - 27.46)
Type IIIa	1 (1.01)	(0.13 - 7.04)
Type IIIb	1 (1.01)	(0.13 - 7.04)
Type IV	0 (0.00)	.
Type V	0 (0.00)	.
Time (days) of endoleak presentation **		
Type Ib	335.125 (0-1826)	.
Type II	197.222 (0-861)	.
Type IIIa	3 (3-3)	.
Type IIIb	861 (861-861)	.
Death	6 (6.06)	
Unruptured aneurysms	4 (4.04)	(2.70 - 13.00)
Ruptured aneurysms	2 (2.02)	

\*\* (Media [Min-Max]).

## 5. Discussion

Endoleaks are the most frequent complication in endovascular repair of infrarenal aortic aneurysms. In the present study the percentage of endoleaks was 28.28%, which is in the range described in previous studies (20-50%) (3).

As published in the literature, the most frequent subtype in our study was type II (18.37 %), a lower percentage than that reported in the systematic review and meta-analysis "Prevalence and risk factors of type II endoleaks after endovascular aneurysm repair: A metaanalysis" with a result of 22 % for type II (13). In contrast to the above, the systematic review by Sidloff et al. included 22 studies in which 1,515 type II endoleaks were documented in 14,794 patients (10.2%). This could be due to the current availability of advanced diagnostic imaging technology that plays an important role in the identification of endoleaks. In the study by Guo et al. the detection of type II endoleaks was significantly higher in the subgroup analysis of studies published after 2010 compared to those published before 2010 (27% vs. 13%) (14).

Type Ia endoleaks in the present study were 7.07 % of patients; in the literature they have been described in up to 11.3 %, but in this work Ib were 8.08 % of patients, i.e., a higher percentage compared to the percentage documented in reference studies (2.6 %) (7). Type III endoleaks have been reported to be approximately 3 % of all endoleaks (3). In the patients of this study, 1.01 % had type IIIa endoleak, lower in relation to that described by Skkiba et al. which was 2.4 % (15). As for type IIIb, the population studied here had a lower percentage (1.01 %) than that found in previous clinical trials (1.6 %) (16). Types IV and V represent 3 % and 3.1 % of all endoleaks, respectively; in contrast, in the population of this study there were no patients with these subtypes (3, 17).

In the analysis of mortality by subgroups, 4.04% was found in patients with unruptured infrarenal aortic aneurysms, lower than that reported in the meta-analysis “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”, which included four multicenter randomized clinical trials, EVAR-1, DREAM, OVER and ACE. These trials showed a mortality of 5.0%, 3.5%, 2.0% and 4.6%, respectively, in patients treated by the endovascular route (17-21). Compared to the overall mortality, in patients who underwent both open and endovascular interventions (6.7%), it was lower (18-22). Further studies with larger sample sizes are needed to establish a relationship between these outcomes and endovascular treatment.

The main limitations of the present study include that it was conducted at a single center, retrospectively. We did not achieve a sufficient sample to reach a statistically significant difference analysis. Additionally, not all eligible patients had data on follow-up, procedure and/or aneurysm characteristics, so they had to be excluded. It is considered that this study serves as a basis for a prospective analytical and multivariate analysis, and if possible, it is recommended to perform future multicenter studies in which a larger sample size is achieved.

## Conclusion

This is the first descriptive study of endoleaks in patients with infrarenal aortic aneurysms managed endovascularly performed in the country. The frequency of endoleak presentation was 28.28%; the most frequent endoleak is type II, 18.37%, slightly lower than that described in the literature.

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