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SAFEGUARD PRESSURE ASSISTED DEVICE FOR LOCAL FEMORAL HEMOSTASIS IN NEUROENDOVASCULAR PROCEDURES: A SINGLE CENTER STUDY OF 879 PATIENTS.

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SAFEGUARD PRESSURE ASSISTED DEVICE FOR LOCAL FEMORAL HEMOSTASIS IN NEUROENDOVASCULAR PROCEDURES: A SINGLE CENTER STUDY OF 879 PATIENTS.

ABSTRACT

Background: Various vascular closure devices (VCDs) are available for local hemostasis after percutaneous transfemoral approach for neuroendovascular procedures but they have been associated with an increased complication rate and limitations to a re-puncture of the artery. We evaluated the safety and efficacy of Safeguard® 24 cm pressure assisted device (Merit Medical, West Jordan, UT, USA) and the associated complications.

Methods: From September 2016 to December 2019, 879 patients underwent neuroendovascular procedures via transfemoral approach using an introducer sheath ranging from 4 to 6-French and they were included in a prospective database. We registered the demographic characteristics and procedural factors. We evaluated the device failure and associated complications.

Results: The Safeguard® was successful in 862 cases (98.1 %) with post-procedural local bleeding in 17 patients (1.9%). On univariate analysis, an association with local bleeding was observed with age >60 years (Odds ratio [OR] = 3.2, ***P* = 0.04**) and the use of an introducer sheath >4F ([OR] = 3.1, ***P* = 0.007**). Female gender, antithrombotic medication and type of procedure (diagnostic or interventional) were not associated with local bleeding. On binary logistic regression analysis, there was association only for age >60 years ([OR] = 3, ***P* = 0.04**).

Conclusion: The Safeguard® 24 cm is safe and efficient. It is simple to use and it can be applied independently from vessel anatomic characteristics. It should though be used with caution in case of a femoral introducer sheath larger than 4 Fr and patients older than 60 years.

INTRODUCTION

The percutaneous transfemoral approach is the most commonly used access for neuroendovascular procedures. Studies, mainly in the field of cardiology, provide evidence that local femoral vascular complications are not uncommon, ranging from less than 1% to 12% [1,2,3,4].

Besides manual compression (MC), various vascular closure devices (VCDs) are available, allowing a shorter time to hemostasis and earlier ambulation. Their use has been associated with an increased complication rate in earlier literature [5]. More recent studies described discordant results with a complication rate, at the access site, for VCD non inferior to MC [6,7,8] or actually significantly lower for newly developed devices [9,10].

Furthermore, it is unclear if it is safe to repeat the puncture of an artery previously managed with a closure device [11]. The use of a totally extracorporeal device, in comparison to the VCDs, could allow a greater flexibility in neurointerventional procedures where often more sessions are necessary for a complete planning, treatment and follow-up, eventually reducing the incidence of femoral complications in case of re-puncture.

Safeguard® 24 cm pressure assisted device, (Merit Medical, West Jordan, UT, USA) is a pneumatic compression device that has been developed for local hemostasis of the femoral artery after brief manual compression.

We evaluated the efficacy of the Safeguard® in a series of 879 patients and we report the complications associated with its routine use following femoral arterial puncture for neuroendovascular diagnostic and interventional procedures.

MATERIALS AND METHODS

From September 2016 to December 2019, 879 patients underwent neuroendovascular diagnostic and interventional procedures in our department, via a percutaneous transfemoral approach, using an introducer sheath ranging from 4-French to 6-French and they were managed by Safeguard in order to achieve local hemostasis. We conducted a retrospective study, based on a prospective database, in order to evaluate the safety and efficacy of the Safeguard Manual Assist Technique in the post angiography local hemostasis management of the femoral percutaneous access.

Safeguard® 24 cm is a pressure assisted single use device with a transparent polyurethane bladder and a pressure sensitive self-adhesive peel backing, developed for local hemostasis by

compression of the femoral artery. A luer valve enables a syringe to be connected to the device in order to inflate the central bladder with 40ml of air and provide pressure to the femoral puncture site.

The study was approved by the local ethics committee and a patient informed consent was obtained in all cases.

Patient exclusion criteria were access site post-procedure complications such as hematoma \geq 6 cm (detected as palpable mass by physical examination), pseudoaneurysm and arterio-venous (AV) fistula (identified by femoral angiography before the introducer sheath removal). Other exclusion criteria included BMI (Body Mass Index) \geq 35 kg/m², excoriation, redness or other signs of inflammation of the skin at the Safeguard application site as well as known allergy to adhesives.

We registered the demographic characteristics and procedural factors such as the femoral introducer sheath size and the single or double antiplatelet (Acetylsalicylic acid and Clopidogrel) or anticoagulant (Warfarin) therapy.

We evaluated the device failure and associated complications. As device failure we defined the absence of complete hemostasis after the first 10 minutes of manual compression directly over the inflated bulb as well as the development of a new subcutaneous hematoma within the first 24 hours. The associated complications included ipsilateral lower extremity ischemia, access site-related infection requiring treatment, retroperitoneal hematoma, local skin excoriation after removal of the adhesive and local allergic reaction.

Arterial access was gained by one of 2 different fellows or by one of 2 attending physicians, one of whom supervised every procedure.

After performing the puncture of the common femoral artery, using the Seldinger technique, a size 4 to 6 Fr introducer sheath was placed.

A Safeguard® 24 cm pressure assisted device, was placed at the end of the angiography using the “Pre-Hemostasis Technique” as described by the manufacturer: initially retreat by approximately 2.5 cm the introducer sheath so that the sheath hub is outside the area of the Safeguard’s adhesive when the latter is adhered to the skin. Successively target and adhere the device on the point of maximum femoral pulse and inflate with 40 ml of air. Remove the introducer sheath and manually compress directly over the inflated bulb up to 10 minutes. In

the cases of device failure, manual compression is maintained until complete hemostasis is assured.

After the positioning of Safeguard®, we periodically control the puncture site and we deflate 20 ml of air two hours later. The device is removed at 24 hours. The puncture site was systematically checked by the interventional team for all patients that continued to be hospitalized at 24 hours, while for the discharged patients late complications have been excluded by telephone.

Statistical analysis

In order to compare the groups with and without post-procedural local bleeding, “age” was expressed as mean and standard deviation and compared with the Mann–Whitney test. “Binary and categorical variables”, reported as counts and percentages, were arranged in contingency tables and studied with the chi square test (with Yates’ correction for 2x2) or, when appropriate, with the Fisher exact test.

The odds ratio OR was computed with its 95% Confidence Interval. Statistical significance was set at two-tails $p < 0.05$. We also analyzed outcomes using binary logistic regression analysis. For this analysis we transformed our continuous variable (Age) in a dichotomous variable using the Receiving Operating Characteristics (ROC) curve.

The Area Under the Curve (AUC) measured the quality of discrimination: conventionally 0.6 corresponds to poor and 1 to excellent.

The threshold between bleeding and no bleeding was set at the “Age” for which three parameters associated with the ROC curve – harmonic mean HM of specificity and sensitivity, Youden index = Sensitivity (SNS) + Specificity (SPC) - 1 were maximum and the distance from the top left corner (SNS=SPC=1) was minimum.

The relation between the two sets of data was explored with Pearson’s linear correlation coefficient r with the associated regression coefficient.

Open source software (www.openepi.com) was used along with Statplus for Macintosh ver. 6 (AnalystSoft, Walnut, CA, USA).

RESULTS

During our study period a total of 879 patients underwent neurovascular diagnostic (cerebral and spinal) or interventional procedures, via a percutaneous transfemoral approach, using a size 4 to 6 Fr introducer sheath and a Safeguard pressure assisted device for local hemostasis.

The interventional procedures, which were all performed with a 6F or smaller introducer, included embolization of brain and spinal tumors, brain and spinal artero-venous fistulas, oropharyngeal hemorrhage, post-traumatic carotid occlusion and intra-arterial treatment of vasospasm.

We have performed a total of 808 diagnostic arteriograms (770 with 4 Fr, 27 with 5 Fr and 11 with 6 Fr introducer sheath) and 71 procedures (6 with 4 Fr, 25 with 5 Fr and 40 with 6 Fr introducer sheath).

Demographic and procedural characteristics of the patient population are presented in Table I.

Table I. Demographic and procedural characteristics

| Characteristics | Without post-procedural local bleeding: n = 862 (98%) | With post-procedural local bleeding: n = 17 (2%) | P value |
|---|--|---|-------------|
| Age (years) | 56.9 ± 13.1 | 64.3 ± 5.7 | 0.02 |
| Female gender | 508 (57.8%) | 13 (76.5%) | 0.23 |
| No therapy interfering with coagulation | 625 (72.5%) | 10 (58.8%) | 0.42 |
| ASA* | 134 (15.5%) | 3 (17.6%) | |
| Clopidogrel | 36 (4.8%) | 1 (5.9%) | |
| ASA + Clopidogrel | 65 (7.5%) | 3 (17.6%) | |
| Warfarin | 2 (0.2%) | 0 (0%) | |
| Sheath size: >4 Fr | 97 (11.2%) | 6 (35.3%) | 0.02 |
| Diagnostic angiography | 795 (90.4%) | 13 (76.5%) | 0.06 |

*ASA : Acetylsalicylic acid

As for the demographic characteristics, the majority of patients were female (521/879) but there was not a statistically significant difference between the group without local bleeding and the group presenting with bleeding ($P = 0.23$).

The patients were more likely to be older in the group with local bleeding ($P = 0.02$) (Fig. 1).

The use of antithrombotic medication was documented in 244 (27.8 %) patients: 137 (15.6 %) were in therapy with ASA, 37 (4.2 %) with Clopidogrel, 68 (7.7 %) with double antiplatelet

therapy (ASA and Clopidogrel) and 2 (0.2 %) patients with Warfarin. There was no statistically significant difference between the two groups presenting with and without bleeding ($P = 0.42$). A flow diagram presenting the cohort of patients with the respective rate of complications (local bleeding) in regard to antithrombotic therapy is presenting in Fig. 2. There has been no periprocedural administration of heparin during our procedures.

The majority of our procedures were diagnostic arteriograms (808/879) and there was no statistically significant difference between the groups with and without bleeding even though it is to point out the border line value of our findings ($P = 0.06$).

The vascular sheath size used was: 4 Fr in 776 cases (88.3%), 5 Fr in 52 cases (5.9%) and 6 Fr in 51 cases (5.8%). In the group presenting with post procedural bleeding, the patients with an introducer sheath larger than 4Fr (> 4 Fr) were more represented with statistically significant difference ($P = 0.02$).

The safeguard device was successful in 862 cases (98.1 %) with post-procedural local bleeding occurring in 17 patients (1.9%). There were no associated complications as these defined in our study.

On univariate analysis, association with post-procedural local bleeding was observed with increased age (> 60 years) (Odds ratio [OR] = 3.2, $P = 0.04$) and with the use of an introducer sheath size larger than 4F ([OR] = 3.1, $P = 0.007$) - Table II.

Table II. Univariate analysis

| | Without post-procedural local bleeding (n = 862) | With post-procedural local bleeding (n = 17) | Odds ratio (95% C.I.) | P value |
|---|--|--|-----------------------|--------------|
| Age >60 years | 372 | 12 | 3.2 (1.1 – 10.0) | 0.04 |
| Female gender | 508 | 13 | 1.3 (0.99 – 1.7) | 0.23 |
| No therapy interfering with coagulation | 625 | 10 | 0.81 (0.54 – 1.21) | 0.33 |
| ASA | 134 | 3 | 1.1 (0.4 – 3.2) | 0.92 |
| Clopidogrel | 36 | 1 | 1.4 (0.2 – 9.7) | 0.79 |
| ASA + Clopidogrel | 65 | 3 | 2.3 (0.8 – 6.7) | 0.28 |
| Warfarin | 2 | 0 | = | >0.99 |
| Sheath size > 4 Fr. | 97 | 6 | 3.1 (1.6 – 6.1) | 0.007 |
| Diagnostic angiography | 795 | 13 | 0.83 (0.64 – 1.08) | 0.06 |

Female gender, use of antithrombotic medication and type of procedure (diagnostic or interventional) were not associated with post-procedural local bleeding.

On binary logistic regression analysis association with post-procedural bleeding included solely “Age > 60 Years” ([OR] = 3, **P = 0.04**) - Table III.

Table III. Binary logistic regression analysis

| | Odds ratio (95% C.I.) | P value |
|------------------------|-----------------------|-------------|
| Age >60 years | 3 (1.04 – 8.6) | 0.04 |
| Sheath size > 4 Fr. | 3.6 (0.84 – 15.7) | 0.08 |
| Diagnostic angiography | 0.85 (0.16 – 4.4) | 0.85 |

DISCUSSION

After catheterization of the common femoral artery, hemostasis of the puncture site can be achieved by MC, External Hemostatic Devices (EHDs) or by the utilization of a VCD.

MC consists in applying targeted manual pressure for at least 10 minutes by a physician or trained staff followed by the application of a compression bandage for 6 hours [6]. The overall post-procedural complication rate for MC is described 1.8 % for 4 Fr [12] and ranges from 7.9 to 9.8 % for 6 Fr introducer sheath [6,8].

Regarding the VCDs, various are available among which: VasoSeal® (Datascope Inc., Montvale, NJ, USA), AngioSeal® (Terumo Interventional Systems, Somerset, NJ, USA), Mynx device (AccessClosure, Inc., Mountain View, CA, USA), Starclose® clip closure system (Abbott Vascular, Redwood City, CA, USA), and Perclose® (Perclose, Redwood City, CA, USA) suture-mediated closure system. They use components (plugs, clips, sutures) to secure the surface of the artery at the point of puncture. Since their introduction in the early 1990s, the use of VCDs has grown exponentially with studies that show reduction in hemostasis time and improvement in patient’s comfort [13,14,15]. Recent studies described discordant results for VCDs with a complication rate, at the access site, non inferior to MC [6,7,8] or actually significantly lower for newly developed devices [9,10]. The overall post-procedural complication rate for VCDs ranges from 6.9 % to 8.6 % for 5 and 6 Fr introducer sheaths [6,8,16].

The EHDs apply external mechanical compression to the arteriotomy site and they include: FemoStop® (Abbott Vascular, Redwood City, CA, USA), QuicKlamp (TZ Medical, Portland, Ore), CompressAR (Advanced Vascular Dynamics, Portland, Ore). The overall post-

procedural complication rate for EHDs ranges from 5.5 % to 10.7 % for 5 and 6 Fr introducer sheaths [17,18,19].

The above mentioned studies have not included the Safeguard® 24 cm pressure assisted device which is classified in the “External hemostatic devices” based on its mechanism of action. In our series of 879 patients treated with the Safeguard® 24 cm pressure assisted device, we have had an overall success rate of 98.1% (1.9 % of hematomas) with no cases of groin infection, lower limb ischemia neither need for vascular surgery even though it is to point out that in most cases a 4 Fr vascular sheath was used. A similar percentage of overall post-procedure complication rate was described at 1.8 % for manual compression regarding only 4 Fr introducer sheaths [12]. In our series, the complication rate for 5 and 6 Fr introducer sheaths was 5.8% (6/103 patients) and regarded exclusively hematomas. This percentage for 5 and 6 Fr introducer sheaths is inferior to the 10.7 % described in a study where an EHD (CompressAR) was evaluated in a cohort of patients consisting of 96.4 % of 5 and 6 Fr (3.5 % of 4 Fr) [19].

Safeguard® and MC have the same mechanism of action and are both used after 4 to 6 Fr introducers making it conceptually easier to compare the two techniques. The VCDs have a different mechanism of action and in clinical practice they are typically used from 6 Fr and above and very rarely for 5 Fr but there is a cohort of patients (with a 5 or 6 Fr introducer) that can be managed with either technique (MC, VSD, Safeguard® or other EHDs).

According to the instructions of use (IFU) of the VCDs, they should be avoided or used with caution in case of uncontrolled hypertension, inflammatory disease, non-common femoral artery introducer sheath placement, small femoral artery size (internal vessel diameter less than 4-5 mm) as well as in the presence of significant peripheral vascular disease, especially with calcification. Instead, for the Safeguard, in consideration of the fact that the device is totally extracorporeal, it is not necessary to worry about the anatomic characteristics of the vessel in terms of femoral artery size or presence of calcifications.

Additionally, it is not clear if an artery can be safely re-punctured when it has been previously instrumented with a VCD [11]. In fact some parts of the occlusion devices can persist perpetually or at least temporarily at the level of the arterial access point. Several manufacturers recommend to avoid re-puncturing the same artery for up to 90 days after VCD deployment in the case of resorbable materials. If a new puncture of the same artery is indicated, this can be performed above the previous access site so as to avoid going through the components of the device previously used. This can be done under fluoroscopic guidance when the components of the VCD previously used are radiopaque, for example the

Starclose® device, or alternatively under ultrasound guidance, as in the case of AngioSeal® where the collagen plug deployed over the arteriotomy is visible as hypoechoic. This evaluation takes time and presumes the knowledge of the type of device previously used, information that may be unavailable. Instead, the Safeguard® does not leave any residual components after removal.

Despite the variety of EHDs it is to point out, regarding Safeguard®, that this “single-use” device is the easiest to place and to remove, the latter being possible even by the patient himself after discharge. The simplicity of its mechanism of action allows the rapid and independent use of the device contrary to other devices which require some degree of training of the staff, with different learning curves. In addition, regarding the cost, it is similar in our center with that of the available VCD but obviously not comparable with the cost of MC.

Nevertheless, based on our clinical experience, the Safeguard®, in comparison to MC, is easier to place (by a single operator) and to remove (even by the patient himself) and requires less time as there is no need to bandage. These advantages apply also in comparison to other EHDs.

To our knowledge there has been a case report of pressure ulceration at the level of the arterial access point in a 95-years old diabetic female after the use of Safeguard® in a percutaneous coronary intervention [20]. The only complication we have had, to date, has been local hematoma at the site of puncture.

We present our overall complication rate for Safeguard® and we have reviewed the literature regarding the complication rates of alternative techniques for the cohort of patients that could be treated in clinical practice with either of these techniques based on the introducer sheath used.

We identified an association between age and post-procedural local bleeding which may prompt to be more prudent with the use of Safeguard® in patients older than 60 years. There was no relation between post-procedural local bleeding and patient's gender or use of antithrombotic therapy.

There has been identified an association between the size of the vascular introducer sheath (>4 Fr) and the post-procedural local bleeding on univariate analysis but not on binary logistic regression analysis.

Based on our experience, the Safeguard® can be used independently of patient gender, antithrombotic therapy (ASA, Clopidogrel, Warfarin) and anatomic characteristics of femoral artery, regarding size and presence of calcifications. It could also be favored in case of probable femoral re-puncture in a short window of time. The use of the device should be

considered with caution in case of an introducer sheath larger than 4 Fr, patients older than 60 years and should be avoided in case of obesity, as the compression force is typically insufficient (Fig. 3).

Limitations of this study include the single-center experience, the lack of a control group as well as the further investigation of eventual risk factors for device failure.

CONCLUSION

The Safeguard® 24 cm is safe and efficient in the setting of neuroendovascular post-procedural femoral access site hemostasis, presenting a success rate of 98.1% and a local bleeding rate of 1.9% according to our study. Its use should be considered with caution in case of a femoral introducer sheath larger than 4 Fr and patients older than 60 years.

Declaration of conflicting interests

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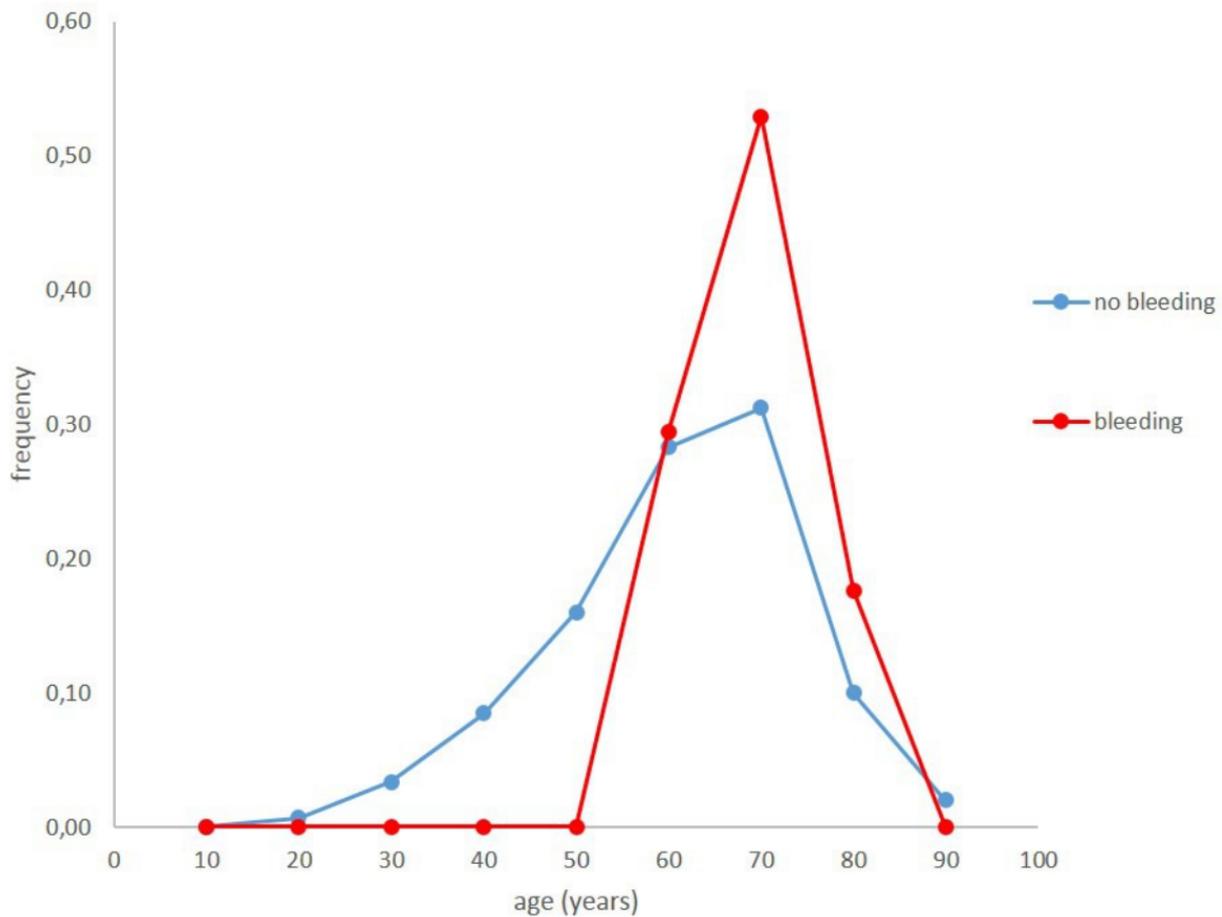
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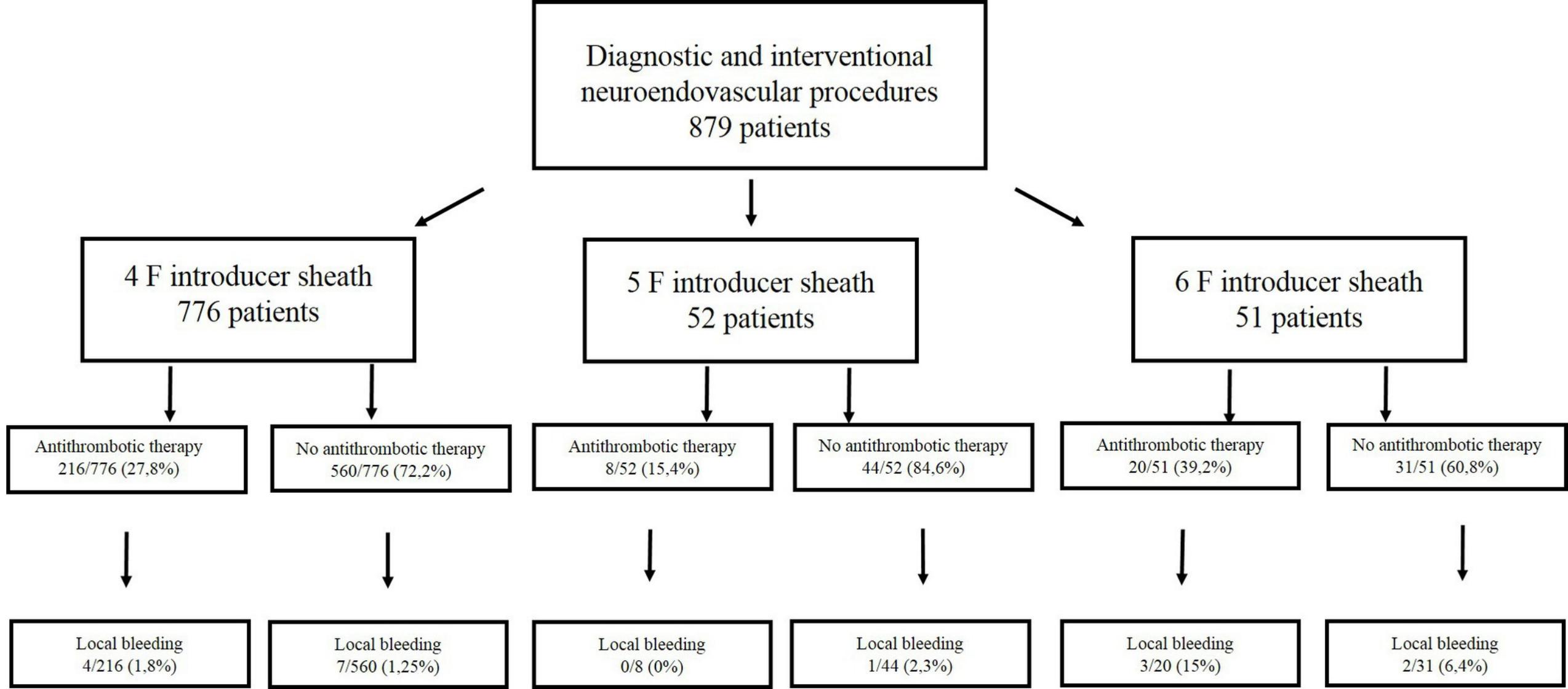
Fig.1 Age frequency distribution

Fig.2 Flow diagram presenting the cohort of patients with the respective rate of complications (local bleeding) in regard to antithrombotic therapy

Fig.3 Recommendations regarding the use of Safeguard® 24 cm pressure assisted device

Age Frequency distribution





Use of Safeguard® 24 cm pressure assisted device

To consider independently of:

To consider with caution in case of:

Gender

Age > 60 years

Therapy interfering with coagulation
(ASA, Clopidogrel, Warfarin)

Femoral introducer sheath > 4 Fr

Anatomical characteristic of femoral artery
(size and calcifications)

Femoral re-puncture
in a short window of time

But to avoid in:
Obesity