



Safety and Efficacy of Peripheral Embolization with EASYX Liquid Embolic Agent: A Multicenter Prospective Study

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Title: Safety and Efficacy of Peripheral Embolization with EASYX™ Liquid Embolic

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Conflicts of interest:

All the authors declared no conflicts of interest.

ABSTRACT

Purpose: The objectives of this study was to evaluate the clinical safety and efficacy of EASYX™, a new non-adhesive precipitating liquid embolic agent based on a polyvinyl alcohol ether polymer grafted with iodine molecules, for peripheral embolization.

Materials and Methods: This open-label prospective multicenter study was conducted on 50 consecutive patients treated with embolization using EASYX™ in 3 academic hospitals from April 2018 to July 2019. Indications for embolization were symptomatic varicoceles ($n=15$), type 2 endoleaks ($n=8$), acute bleedings ($n=16$), or portal vein embolizations (PVE; $n=9$), angiomyolipomas (AML; $n=2$). Patient characteristics, technical and clinical success rates, pain at injection and interventional radiologist (IR) satisfaction were assessed. Follow-up imaging was performed using ultrasound for varicoceles (at 1 month) and CT-scan for the other indications (at 3 or 6 months).

Results: Immediate technical success was 98%. Clinical success was 100% for acute bleedings and type 2 endoleaks, 89% for PVE, 86% for varicoceles and 50% for AML. PVE patients showed a significant hypertrophy of the future liver remnant at follow-up ($P < 0.001$) and 55.6% of the patients could undergo preplanned hepatectomy. Absence of artifacts on imaging allowed optimal monitoring of the aneurysmal sac in patients treated for type 2 endoleaks. IR satisfaction was >90 % for 5/7 items.

Conclusion: EASYX™ as a novel copolymer liquid embolic agent was safe and efficient for peripheral embolization. The absence of tantalum allowed reduced CT artifacts on imaging follow-up, which is especially useful in patients with type 2 endoleaks.

Keywords

Interventional Imaging; Peripheral embolization; Liquid embolics; Prospective study

TEXT

INTRODUCTION

Percutaneous transcatheter embolization is part of the daily work of all interventional radiologists (IR) worldwide. With accumulated experience and improvement in the design of embolic agents and devices, embolization has become the treatment of choice for many vascular abnormalities (1). Among the different embolic agents, liquid embolics are used when a rapid, complete and permanent vessel occlusion is required. These materials are injectable in liquid form and solidify once delivered in the vasculature. Their mechanisms of solidification and radiopacity characteristics are key features with a large influence on practical performance of the product (2). According to Vanninen et al., the ideal liquid embolics yield rapid and effective embolization, have the ability to reach and fill distal vasculature targeted for embolization, is easy to prepare and use, is highly radiopaque, controllable during administration, biocompatible, and cost-effective (3). Up to a recent period, two types of liquid embolics have been mostly available: cyanoacrylate-based (NBCA) glues and ethylene vinyl alcohol copolymers (4–7).

The EASYX™ Liquid Embolic is a new injectable, precipitating polymeric agent for the obliteration of vascular spaces through direct puncture or catheter vascular access performed under X-ray guidance. The liquid embolic is an iodinated polyvinyl alcohol (PVA) ether polymer. Iodine groups are covalently bounded to the PVA polymer backbone, whereby a stable non-degradable polymer with the desired features is created. The resulting polymer is dissolved in DMSO. A preclinical animal study on 26 pigs concluded to a feasible and effective embolization without any safety and

technical issues but no study has been reported with the use of EASYX™ in humans yet (8).

Under the new European Medical Device Regulation, clinical data of good quality are mandatory to obtain and sustain the European Community (CE) marking (9). It is in this context that the present study was set up. The purpose of this clinical study was to assess the safety and efficacy of EASYX™ liquid embolization agent for the percutaneous and/or endovascular treatment of several types of vascular conditions, such as varicoceles, type II endoleaks, portal veins before hepatectomy, arterial hemorrhage and angiomyolipomas (AML).

MATERIALS AND METHODS

Study Design

The EASYX 1 study was a multicenter, prospective, open-label phase 2 study performed in 3 centers in [REDACTED] (ClinicalTrials.gov Identifier : [REDACTED] (10). The sponsor was [REDACTED] ([REDACTED] [REDACTED] designed the study, gathered and analyzed the data, vouches for the data and analysis, wrote and decided to publish the paper.

The study was funded by a grant from [REDACTED]. It received Ethics Committee approval ([REDACTED] [REDACTED]) and informed consent was obtained from all patients prior to inclusion.

Participants

Inclusion criteria consisted in patients aged ≥ 18 years and presenting with symptomatic varicocele, type II endoleak, liver tumor necessitating preoperative PVE before liver resection, AML needing prophylactic embolization or active bleeding.

Exclusion criteria were as follows: patients participating in another interventional study, pregnant or breastfeeding women, patients unable or unwilling to provide a written informed consent and patients with known hypersensitivity to PVA polymer and/or DMSO solvent.

A total of 50 consecutive patients were included between April 2018 and July 2019.

Indications and clinical symptoms are detailed in Table 1.

Study Device

The EASYX™ Liquid Embolic (Qmedics, Zurich, Switzerland) is a new injectable, precipitating polymeric agent for the obliteration of vascular spaces through direct puncture or catheter vascular access performed under X-ray guidance. The liquid embolic is an iodinated polyvinyl alcohol (PVA) ether polymer. Iodine groups are covalently bounded to the PVA polymer backbone, whereby a stable non-degradable polymer with the desired features is created. The resulting polymer is dissolved in DMSO.

Embolization Technique

Embolization was performed according to the Society of Interventional Radiology (SIR) guidelines for percutaneous transcatheter embolization for each indication (1).

EASYX™ was injected through a DMSO compatible microcatheter after a prepping of

the dead space with DMSO to prevent precipitation of the embolization material during injection according to instructions for use. No pre-embolization shaking of the EASYX™ vials was necessary. All 3 principal investigators (PIs) underwent preclinical training on animal models before entering the trial. Co-investigators were selected after appropriate experience with the device's use according to the PI of each center. A total of 8 different interventional radiologists used the device for the study purpose.

Initial Evaluation and Follow-up

All patients were followed at 1 and 6 months after embolization. In addition, PVE and AML patients were respectively followed at 2 months (or before hepatectomy) and 3 months post-embolization.

The efficacy primary endpoint was the percentage of clinical success depending on the indication. The clinical success in case of active bleeding embolization was defined as the complete occlusion of the target vessel assessed by angiography during the index procedure. The clinical success of type II endoleaks embolization was defined as the stability or reduction of aneurysm's both antero-posterior (AP) and transverse (TR) maximal diameters on CT-scan at 6 months compared to baseline (4-mm threshold).

Concerning PVE patients, a growth $\geq 15\%$ of the future liver remnant (FLR) assessed on presurgical CT-scan compared to baseline was considered as clinical success. The clinical success of varicocele embolization was defined as the absence of reflux on ultrasound Doppler at the 1-month follow-up. The clinical success of AML embolization was defined as the reduction $>10\%$ of at least one diameter on MRI or CT-scan at 3 months follow-up compared to baseline.

The primary safety endpoint was the expected and unexpected per-procedure serious adverse events (SAE) related to the EASYX™ use (accountability "certain" or "probable") as adjudicated by an independent critical events committee. Adverse events' causality and severity were graded according to WHO-UMC (World Health Organization and Upsala Monitoring Center) causality categories and CIRSE classification system for complications (11,12).

The secondary endpoints, both global and per indication, included the description of AE/SAE related to the device, survival rates, pain, immediate technical success, EASYX™ volume and IR immediate technical satisfaction questionnaire.

Statistical Analysis

No formal sample size calculation was needed as Bayesian inference was used for the analysis of the primary endpoints (13). A sample size of 50 subjects (about 10 in each indication) was sufficient to provide significant prospective analysis of safety and efficacy of EASYX™ embolization liquid. The Bayesian approach permitted to provide stopping rules of the study in case of the occurrence of too many SAE attributable to the device.

Statistical analysis was performed using R software (R Foundation for Statistical Computing, Vienna, Austria). Quantitative variables were expressed as mean \pm standard deviation (SD) and range. Qualitative variables were expressed as raw numbers (n), proportion and percentages (%). The principal analysis was performed in the intention-to treat basis and included all evaluable patients. Missing data were not imputed. Mean of variables before and after the procedure were compared using a

paired sample Mann-Whitney test. Statistical significance was established for *P* values less than 0.05.

RESULTS

Study Population

A total of 51 consecutive patients signed EASYX 1 informed consent and 50 patients were embolized with EASYX™. Forty patients (80%) completed the study at the 6-month follow-up as required per-protocol. Four patients (8%), all in the active bleeding group, were lost to follow-up (last visit: 0, 0, 23, 27 days post-embolization) and 6 patients (12%) died before the last study visit (6 months). Three patients died in the PVE group (at 35, 38 and 149 days post-embolization) and 3 in the active bleeding group (at 2, 4 and 65 days post-embolization). All deaths were adjudicated as the normal evolution of the index illness by the independent critical events committee, and the death was not related to the use of the embolic agent in any case.

Technical and Clinical Results

Mean number of ampoules of EASYX™ needed for embolization was: 1.5 ± 0.71 for AMLs, 1.75 ± 1.06 for arterial hemorrhage, 2.67 ± 1.45 for varicoceles, 4.88 ± 1.89 for type 2 endoleaks and 7.33 ± 2.4 for PVEs ($P < 0.001$). In 2 active bleeding patients, gelfoam or micro-coiling was used to protect non-target arteries before EASYX™ embolization. Addition of another liquid embolic agent was not required during the study. Pain during injection was collected using a 0 to 10 cm visual analog scale (VAS) in patients under local anesthesia. Mean pain score was 0.5 ± 1.41 cm (range, 0-4) for

type 2 endoleak, 1.6 ± 2.59 cm (range, 0-8) for active bleeding, and 5.03 ± 2.11 cm (range, 2-8) for varicocele. Pain started during injection and lasted a few minutes after injection. In all cases, pain was easily managed conservatively.

Immediate technical success defined by complete occlusion of the target vessel(s) as assessed on the final angiogram was obtained in 49 (98%) of the 50 patients (figure 1 and 2). In one type II endoleak patient, the aneurysmal sac was occluded at 90% at the end of the procedure. No re-intervention on the target vessel(s) was required.

Interventional radiologist immediate technical satisfaction is described in Table 2 through a specific questionnaire.

Clinical success and results per indication are described in Table 3 and Table 4, respectively.

Complications and Follow-up

No (6/7) or minor (1/7) artifacts on CT-scan were observed at the 6-month follow-up in type II endoleaks. Upon PVE with clinical success ($n=8$), mean FLR absolute growth at FU was $44 \pm 20.4\%$ (range, 20–88%).

During the study, 3 major complications related to the device occurred in 2 patients as adjudicated by the independent critical event committee. In one patient presenting for acute bleeding related to a pseudo-aneurysm of the common hepatic artery, a distal embolization of the gastro-duodenal branches led to an acute pancreatitis responsible for a prolonged hospital stay for 12 days and complication grade 4 according to the CIRSE classification. This patient was in severe condition related to a type 4 vascular Ehler-Danlos disease and only liquid embolics could be used, with no possibility for

distal coil protection because of the fear of arterial rupture during coil delivery. The non-target embolization was attributed to the device with the highest grade (certain) by the committee. This patient also had a short and moderate fever episode (38.4°C) 6 days after the embolization that was spontaneously resolute without any medication, likely due to acute pancreatitis.

One patient referred for renal AML embolization experienced 2 complications attributable to the device use. A non-target embolization led to the complete occlusion of the renal artery, which resulted in acute kidney failure requiring hemodialysis (grade 4 according to the CIRSE classification). The non-target embolization was attributed to the device with the highest grade (certain) by the committee. For this patient, embolization was unsuccessful with an increase of the AML diameter from 54 mm to 100 mm at follow-up (126 days).

EASYX™ minor reflux was observed in 3 patients with no clinical or symptomatic complication. After a left PVE, a reflux was seen in the right portal vein on control angiography. A reflux of small amounts of EASYX™ was observed on the final angiogram in the inferior vena cava on the needle track after a transcaval embolization of a type II endoleak. This small piece of EASYX™ device migrated to the right lower lobar pulmonary artery as observed on the 6-month CT-scan follow-up, with no associated symptoms. Lastly, a non-target embolization of the inferior mesenteric artery in the downstream of the left colic artery was observed in one patient embolized for a type II endoleak with no clinical consequence.

DISCUSSION

In this prospective multicenter study, promising results using EASYX™ for embolization in various clinical situations were reported. Immediate technical success was obtained in 49 (98%) of the 50 patients and IR satisfaction was >90% for EASYX™ ease of use, ease of injection, cohesivity and overall angiographic results. Only 3 complications related to the device were reported. No allergy was described.

These results reflect the global satisfaction of the IRs while using the device. The fact that EASYX™ is a ready-to-use device was one positive feature, allowing potentially faster intervention in contrast to need for 20 minutes shaking required before injection for other copolymers containing tantalum (4). This aspect can be advantageous when a very rapid administration is necessary, especially for acute bleeding patients.

Regarding ease of injection and cohesivity, the IRs feelings were comparable to other EVOH liquid embolics. Radiopacity / visibility was lesser than in embolic devices containing tantalum powder leading to 88% good/average satisfaction on this item.

This lesser visibility may have contributed to the non-target occlusion of the renal artery in the patient with AML indication who experienced cascade complications, but the learning curve may also have been partly responsible for this poor outcome.

The relative lower radiopacity of EASYX™ as compared to tantalum-based agents was not perceived as a major drawback but was turned into a compelling advantage in case where CT follow-up is important. It is well known that beam hardening artifacts related to the high content in tantalum prevent clinically efficient CT follow-up with other EVOH based agents (4,14). Indeed, this can be a serious limitation in assessing the recurrence of acute bleeding or the persistence of aneurysmal sac feeling in type II endoleaks.

The global safety of using EASYX™ was good in the present study. Reflux of a small amount of EASYX™ with no associated clinical symptoms was observed in 3 patients. It is one of the known complications when using liquid embolic agents (6). In this prospective study, no toxic effects of DMSO solvent were reported despite the use of up to 12 ml of EASYX™ (15).

When assessing the efficacy of EASYX™, the recurrence rate was 12.5% at one month in the varicocele embolization group, which is comparable to surgery but also to the results described for embolization with sclerosants and coils, alone or in combination (16,17). Embolization with glue seems to provide better results with a mean 4.2% (range, 0-11%) recurrence rate in the review by Makris et al. but the authors described perforation of the internal spermatic vein with contrast extravasation in 5.8% of patients, that was not experienced in the present study (18). Additionally, glues are responsible for acute and chronic inflammation, releases heat when polymerizing and toxic by-products such as formaldehyde, a known reprotoxic molecule, which is a concern in varicocele management, especially in the context of infertility (2,5). Upon frequent complications (3.4 %) after varicocele embolization with coils are epididymo-orchitis, pampiniform plexus phlebitis or hydrocele, none of the patients in this study experienced any of these complications, possibly related to the high viscosity of EASYX™ (18). A good efficacy of embolization for painful varicoceles was also described with a drastic decrease of the VAS score at one month. Pain reduction is rarely evaluated in varicocele embolization while painful varicoceles are an important part of the referral, possibly because most studies are retrospective (18).

Regarding the PVE group, the clinical success rate was 89% at one-month follow-up with a mean FLR absolute growth of 44%, which is even higher than the usual growth reported after PVE with most of other occlusive devices (19). Only 5 of the 9 patients could undergo hepatectomy but 2 of the 4 patients who didn't benefit from hepatectomy died 35 and 38 days after PVE because of their underlying cancer disease, i.e. before the planned surgery (20,21). Although the study was prospective, none of the known complications of PVE such as severe cholangitis, large abscesses and sepsis, portal venous or mesentericoportal venous thrombosis were described (20).

Only 2 patients were included in the AML group because of the small number of patients usually referred for this indication in the 3 investigative centers and because of the major complication that occurred in the second AML patient after a non-target embolization of the renal artery. The first patient showed a significant volume reduction. Nonetheless, good results are described in the literature with other copolymers (22).

In the acute bleeding group, per-procedure clinical success was 100% since the target vessels were completely occluded. Two patients died few days after the embolization and one patient after one month. These results are in line with mortality rates reported in the literature for this indication (23). No rebleeding from the target vessels were experienced.

The technical and clinical success were respectively > 98% and 100% for type II endoleaks embolization on imaging follow-up at 6 months with no complication, , which is better than the results previously reported (24). The absence of artifacts on CT

allowed precise measurement of the sac and evaluation of persistent endoleak during follow-up, which is very helpful for optimal surveillance of the aneurysm (25).

Finally, it is of interest that the use of the Bayesian approach in this study allowed us to ensure appropriate assessment of the device safety and efficacy, in a wide range of indications. This approach is one of the “innovative ideas” proposed by Sedrakyan et al. for the evaluation of medical devices in which randomized control trials are difficult to consider (10). Because the new European regulation on medical devices called for appropriate clinical validation before CE mark approval, this Bayesian approach could be of interest for the evaluation of other embolic devices (9).

This study had some limitations. First, the small number of patients in some indications. Second, the heterogeneity of indications. Third, the short-term global follow-up. Last, in terms of device development, the single available viscosity of EASYX™ was used. It might be of interest to have a lower viscosity for some other indications such as peripheral arteriovenous malformations. For all these reasons, larger studies with longer follow-up are warranted.

In conclusion, the use of EASYX™ as the main liquid embolic agent for peripheral embolization was safe and efficient in several indications. The safety and performance results of EASYX™ were satisfactory in this initial prospective multicenter trial. Absence of CT imaging artifacts (no tantalum powder in the device) allowed optimal follow-up of type II endoleaks, representing a major advantage over other liquid embolic agents.

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LEGENDS

Figure 1. CBCT of spermatic vein after coiling and embolization with Easyx™.

Varicocele vein was 100% occluded and because Easyx™ contains no tantalum, no beam artifacts were seen, comparing favorably to the the artefact around the coils that had been previously implanted.

Figure 2. Angiographic images before (A, C) and after (B, D) embolization with Easyx™ in a transplanted kidney requiring embolization for an arterial hemorrhage after a biopsy (A, B) and a 6 cm AML (C,D). (A) Active extravasation of contrast media from a small branch at the upper pole of the kidney. (B) Total occlusion of the feeding artery after embolization with Easyx™. (C) Visualization of AML before embolization. (D) AML exclusion after embolization.

Table 1. Patient Population.

Table 2. IR satisfaction while using EASYX™ in the 50 patients.

Table 3. Clinical success per indication.

Table 4. Clinical results per indication.

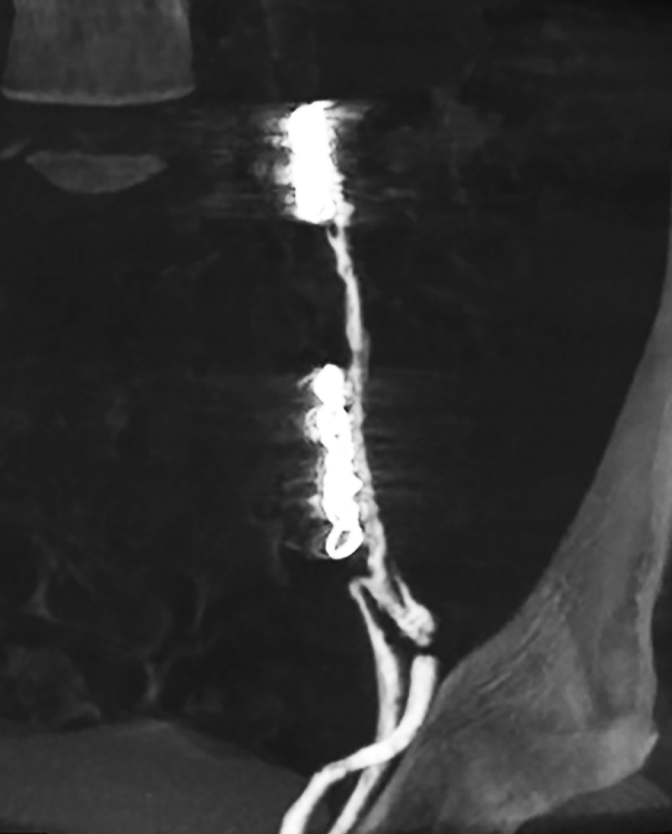










Table 1. Patient Population.

Indication	Varicocele (n=15)	PVE (n=9)	Acute bleeding (n=16)	Type II endoleak (n=8)	AML (n=2)	All (n=50)
Age (years)	33 ± 9 (18-52)	72 ± 10 (50-83)	62 ± 20 (22-95)	72 ± 9 (61-84)	53 ± 18 (41-66)	56 ± 21 (18-95)
Male/Female	15/0	6/3	11/5	8/0	1/1	41/9
Clinical indication details	- -Pain (n=11) -Infertility (n=5)	- Hepatocellular carcinoma (n=1) - Cholangiocarcinoma (n=3) - Colorectal metastases (n=5)	-Kidney (n=5) -Lung / chest (n=3) -Soft tissue (n=2) -Upper GI / liver (n=6)	Aneurysm diameter: max AP: 55 ± 8 mm (48- 73) max TR: 55 ± 9 mm (46- 74)	AML diameters : 54mm, 30mm	

		FLR volume: 529 ± 299 ml (210- 800)				
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PVE, portal vein embolization; AML, angiomyolipoma; FLR, future liver remnant; GI, gastrointestinal; AP, antero-posterior; TR, transverse. Data are expressed as n (%) or mean±SD (range).

Table 2. IR satisfaction while using EASYX™ in the 50 patients.

Q1. Did you obtain the result you anticipated? ○ Yes ○ Partially	46 (92) 4 (8)
Q2. How would you describe the ease to use? ○ Good ○ Average	47 (94) 3 (6)
Q3. How would you describe the ease of injection? ○ Good ○ Average ○ Bad	46 (92) 3 (6) 1 (2)
Q4. How is cohesivity? ○ Good ○ Average ○ Bad	48 (96) 1 (2) 1 (2)
Q5. How is radiopacity / visibility? ○ Good ○ Average ○ Bad	31 (62) 13 (26) 6 (12)
Q6. How would you describe the intervention's results in general? ○ Good ○ Average	46 (92) 3 (6)

○ Bad	1 (2)
Q7. Would you reproduce the same intervention?	
○ Yes, with EASYX™	39 (78)
○ Yes, with another liquid embolic	8 (16)
○ No, not with a liquid embolic	3 (6)

Q, question; Data are expressed as n (%).

Table 3. Clinical success per indication.

Indication for embolization	Clinical success definition	Percentage of success	Mean follow-up (days)
Type II endoleak	Stability or reduction of aneurysm's diameters	100% (7/7)	184 ± 29
Portal vein embolization	Growth ≥15% of the remnant liver at presurgical CT-scan	88.9% (8/9)	29 ± 13
Varicocele	Absence of reflux on ultrasound Doppler	85.7% (12/14)	38 ± 12
Angiomyolipoma	Reduction >10% of AML diameter	50% (1/2)	134 ± 12
Active bleeding	Complete occlusion of the target vessel at index procedure	100% (16/16)	NA

Data are expressed as percentage (n) or mean ± SD.

Table 4. Clinical results per indication.

	Value at baseline	Value at FU	P	FU (days)
Type II endoleak (<i>n</i> =7)				
Aneurysm diameter (mm):				
○ Antero-posterior	53 ± 4 (48-58)	51 ± 6 (42-57)	<i>P</i> =0.61	184 ± 29
○ Transverse	53 ± 4 (46-58)	51 ± 5 (46-57)	<i>P</i> =0.52	
PVE (<i>n</i> =9)				
• FLR volume (ml)	530 ± 210	740 ± 348	<i>P</i> <0.001	29 ± 13
• Liver surgery done at FU		55.6% (5/9)		46 ± 17
Painful varicoceles (<i>n</i> =11)				
Pain evolution (VAS score: 0-10 cm)	5.18 ± 1.76	1.05 ± 1.39	<i>P</i> <0.001	38 ± 12
Angiomyolipoma (<i>n</i> =2)				
Axial diameter (mm; exact value):				
○ Success of embolization	30	17	AML decrease	143 days

○ Failure of embolization	54	100	AML growth	126 days
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FU, follow-up; FLR, future liver remnant; PVE, portal vein embolization; VAS, visual

analog scale; Data are expressed as percentage (n) or mean \pm SD (range).