Impact Surgery

Original Research Paper

e-ISSN: 3033-4470

The influence of ultrasound in the choice of surgical technique to repair inguinal hernia: a prospective multicentre cohort study

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Abstract

Background: Inguinal hernia is diagnosed by physical evaluation alone in most patients. Although imaging should be reserved for equivocal physical findings, a previous cohort study described a high rate of ultrasound usage. This study aimed to explore the association between ultrasound usage and the choice of surgical technique to repair inguinal hernia.

Methods: This was a multicentre prospective cohort of consecutive patients undergoing elective inguinal hernia repair between October and December 2019. The group of patients diagnosed with physical evaluation was compared to the group diagnosed with ultrasound. Patients undergoing other imaging tests were excluded. The primary outcome was surgical technique and a multivariable logistic regression model was used to test its association with ultrasound use

Results: A total of 911 patients from 33 Portuguese hospitals were included, of which 49.2% (448) were diagnosed with physical evaluation and 50.8% (463) with ultrasound. There were no statistically significant differences in the characteristics of the patients, symptoms or hernia type between the two groups. Lichtenstein was the most used surgical technique in both groups. There was no association between the use of ultrasound and the choice of surgical technique (adjusted odds ratio 1.02, 0.71-1.48, p=0.901).

Conclusion: Although ultrasound is not recommended routinely for diagnosing inguinal hernia, it was used in half of the patients and demonstrated no impact on the choice of surgical technique. A national intervention needs to be planned to decrease the use of ultrasound in inguinal hernia, reducing the costs for the patients and the healthcare system.

** Full list of PubMed citable authors available in Appendix 1*

Cite as: PT Surg. The influence of ultrasound in the choice of surgical technique to repair inguinal hernia: a prospective multicentric cohort study. *Impact Surgery*, 2(3), 73–81. https://doi.org/10.62463/surgery.144

Introduction

Inguinal hernia repair is one of the most common operations worldwide. It has a lifetime risk that increases with age [1-2], so management and repair are essential to decrease the number of associated disability-adjusted life years [2,3,4]. For most patients, the recommended surgical technique includes the use of mesh [5]. In both female and male patients with primary unilateral inguinal hernia, a laparoscopic approach can reduce both postoperative and chronic pain, as well as accelerate recovery time [5]. Nevertheless, these techniques have a longer learning curve and require a higher degree of training and expertise [5-6]. The Lichtenstein technique (a tension-free open mesh repair) has been shown to have similar complication rates, with a more favorable learning curve, justifying its wider adoption [5-6].

Inguinal hernia is a clinical diagnosis, where adequate history and physical evaluation are usually sufficient [6]. In doubtful cases (i.e., diffuse groin pain or vague groin swelling), ultrasound is the recommended imaging method for diagnosis, with a high positive predictive value and a sensitivity of 86% and specificity of 77% [6,7,8]. In Portugal, the use of preoperative ultrasound was reported to be 48.88% in a cohort study of patients diagnosed with inguinal hernia [4] but the impact of ultrasound usage in patient's treatment hasn't been explored. Although ultrasound might have a role in an emergency setting (to identify predictors for emergent intervention), there is limited benefit in its use in elective setting [6, 7-12].

Previous studies have shown that ultrasound influenced surgical decision in 4.8% of patients [12]. The decision to proceed to surgery based on physical evaluation findings alone occurred in 81.9% of cases, whereas the decision based only on ultrasound findings occurred in 1.5%. Therefore, preoperative ultrasound seems to have limited surgical value [12, 13]. When analysing data from Portugal, there is a high expenditure associated with imaging exams, especially when these are sponsored by the government but performed in the private sector. However, the exact costs of using ultrasound when it is not recommended are hard to estimate [14, 15] as this problem has not been properly addressed.

Although literature and current recommendations support physical evaluation as a sufficient diagnostic method for inguinal hernia, the rate of preoperative ultrasound remains high in Portugal, with uncertain clinical benefits. The primary aim of this study was to evaluate the use of ultrasound in guiding the choice of surgical technique for inguinal hernia repair. The secondary aim was to assess the factors that could be contributing to the use of ultrasound to diagnose inguinal hernias.

Methods:

Study Setting and Design

The Portuguese Inguinal Cohort (PINE) study was a prospective multicentric cohort study which evaluated postoperative chronic pain and its associated risk factors in patients undergoing inguinal hernia repair. It was registered at Clinicaltrials.gov (reference: NCT04328597) and the protocol is available [16]. Each hospital obtained approvals from its local Ethics Committee and individual

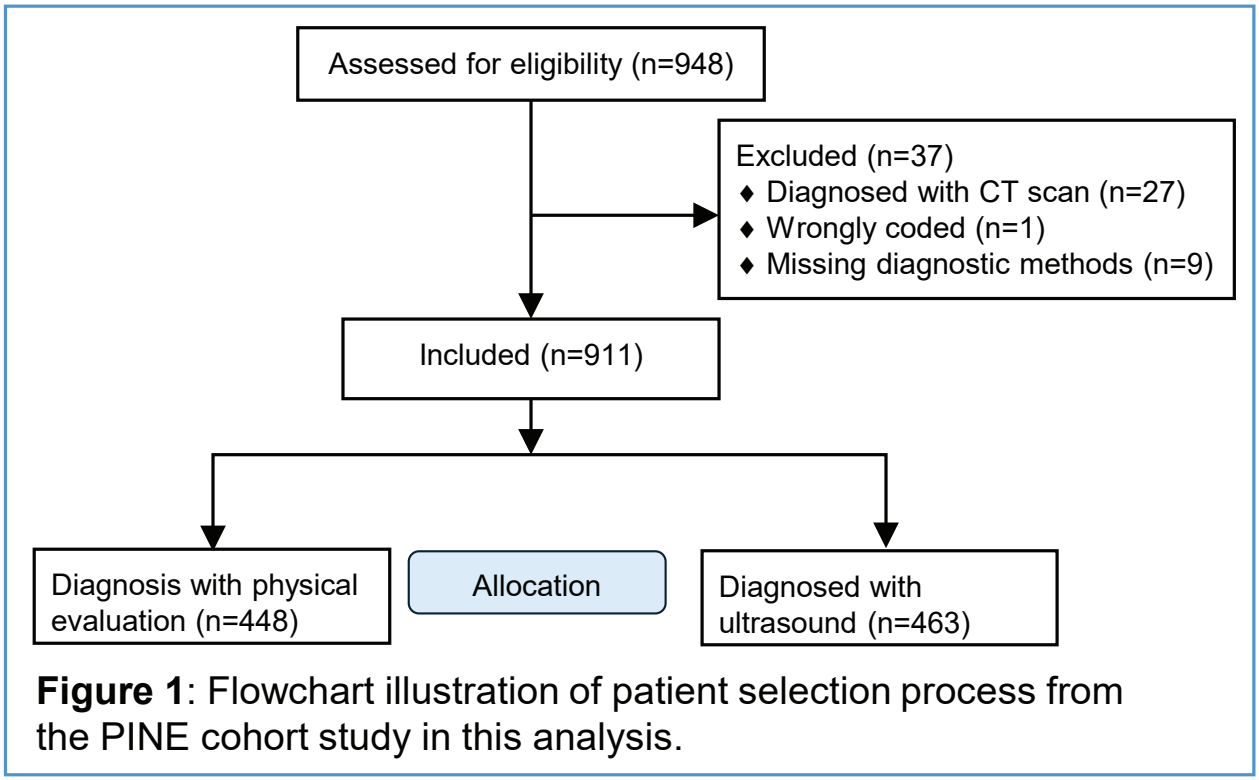

Figure 1: Flowchart illustration of patient selection process from the PINE cohort study in this analysis.

patient consent. Any Portuguese hospital that performed elective inguinal hernia surgery could take part. Data was collected in 14-day consecutive periods within the study window which was from 7th October to 13th December 2019.

Inclusion and Exclusion Criteria

All consecutive patients over 18 years of age, who were submitted to elective inguinal hernia repair, able to consent, and able to keep follow-up compliance, were eligible to take part. Follow-up compliance was defined as the ability to answer a questionnaire to assess the quality of life via a telephone call. Patients diagnosed by physical evaluation or ultrasound were included in this analysis (figure 1). Patients who underwent other preoperative imaging methods (i.e., CT, MRI, herniography) were excluded from this analysis (figure 1), as well as emergent or urgent surgeries. Information regarding the type of diagnosis (clinical vs. imagological) was obtained at each participating site from patient records.

Outcome Measures

The primary outcome of this study was surgical technique. All surgical techniques were eligible. As previously described in the first analysis from the PINE Study, Lichtenstein's technique was the most used surgical technique in elective inguinal hernia repair in Portugal [4]. Considering Lichtenstein is the recommended technique for inguinal hernia repair [5,6], patients were categorized as Lichtenstein versus Others. The latter category included open repair with mesh (trans inguinal preperitoneal, transabdominal pre-peritoneal, plug and patch, prolene hernia system, and variations of these repairs), open repair without mesh (Shouldice, Bassini and Desarda repairs) and laparoscopic repair with mesh (totally extraperitoneal, transabdominal preperitoneal, single incision laparoscopic repair and robotic) procedures. The primary outcome of this study was undergoing surgery using the Lichtenstein technique.

Data Variables and Definitions

Demographic and patient characteristics were included within the preoperative variables: age, sex, body mass index (BMI), American Society of Anesthesiologists (ASA) physical status (Appendix 3), smoking status, smoking packs per year, comorbidities. Preoperative inguinal pain was defined as a preoperative assessment score of ≥ 3/10 in the questionnaire from the European Hernia Society Quality of Life (EuraHS-QoL) (Appendix 3). Within the intraoperative variables, surgical technique (Lichtenstein versus others), hernia size (<1,5 cm versus >1,5 cm), type of mesh (heavy versus light), mesh fixation (absorbable versus non-absorbable), anesthesia type (general versus local) and service delivery strategy (admission versus day-case) were described.

Data collection and management

Pre and intraoperative data were collected by local teams directly from the patient and complemented with clinical records, at the time of the admission and surgery. Each participating hospital had a local team that was coordinated by a local lead. Each team was responsible for the recruitment (of all consecutive patients undergoing elective inguinal hernia surgery in the chosen data collection period), for data collection and upload. All local teams and local leads were coordinated by the operations committee of the study, which were General Surgery trainees and consultants in Portugal. This committee was also responsible for the study design, study dissemination and management (detailed in Appendix 1). All data were stored in a secure and anonymized platform - Research Electronic Data Capture (REDCap). Missing data are reported in the figures and tables of the present article. Patients with missing data on the included variables were excluded from the models and were reported.

Statistical analysis

Categorical variables were described and summarized in frequency tables. Continuous variables were described with mean and 95% Confidence Interval (CI), if normally distributed, or with median and interquartile range (IQR) if not. A multilevel multivariable logistic regression model was implemented to test the association of patient characteristics and the use of ultrasound. Clinically plausible variables which could challenge a clinical diagnosis of inguinal hernia were selected and included: age, sex, Body Mass Index (BMI), previous history of inguinal hernia, surgical indication (asymptomatic or symptomatic) and preoperative inguinal pain. To test the association of ultrasound and choice of surgical technique, a multilevel multivariable logistic regression model was conducted. Variables that could potentially change the surgeon's approach were included in the model: preoperative imaging, gender, hernia laterality, hernia size and previous history of inguinal hernia were included. Statistical significance was defined as p-value <0.05. Data were analyzed with R studio, version 4.3.1.

Results:

A total of 911 patients from 33 Portuguese hospitals were included, with a mean age of 61 years (SD 14.2). Inguinal hernia was diagnosed with physical evaluation in 49.2% (448/911) patients and with ultrasound in 50.8% (463/911) patients. The main reason for the exclusion of patients was diagnosing the inguinal hernia with a CT scan.

Most patients were male (90.0% (820/911)). The most frequent presentation was symptomatic (68.87%

Table 1: Description of patient characteristics and demographic data.

		Physical evaluation (n=448)	Ultrasound (n=463)	Total (n=911)
Age	Mean (SD)	62.1 (14.1)	59.9 (14.2)	61.0 (14.2)
Sex	Female	37 (8.3%)	52 (11.2%)	89 (9.8%)
	Male	409 (91.3%)	411 (88.8%)	820 (90.0%)
	(Missing)	2 (0.4%)	0 (0.0%)	2 (0.2%)
BMI	Normal	202 (45.1%)	194 (41.9%)	396 (43.5%)
	Underweight	3 (0.7%)	9 (1.9%)	12 (1.3%)
	Overweight	188 (42.0%)	199 (43.0%)	387 (42.5%)
	Obese	41 (9.2%)	50 (10.8%)	91 (10.0%)
	(Missing)	14 (3.1%)	11 (2.4%)	25 (2.7%)
ASA grade	ASA 1-2	357 (79.7%)	387 (83.6%)	744 (81.7%)
	ASA 3-4	89 (19.9%)	75 (16.2%)	164 (18.0%)
	(Missing)	2 (0.4%)	1 (0.2%)	3 (0.3%)
Smoking Status	Ex-smoker	89 (19.9%)	101 (21.8%)	190 (20.9%)
	No	260 (58.0%)	252 (54.4%)	512 (56.2%)
	Yes	98 (21.9%)	110 (23.8%)	208 (22.8%)
	(Missing)	1 (0.2%)	0 (0.0%)	1 (0.1%)
Comorbidities	Ascites	3 (0.7%)	1 (0.2%)	4 (0.4%)
	Asthma	9 (2.0%)	8 (1.7%)	17 (1.9%)
	COPD	23 (5.1%)	23 (5.0%)	46 (5.0%)
	Cardiac Ischemic Disease	27 (6.0%)	29 (6.3%)	56 (6.1%)
	Cardiac Valve Disease	7 (1.6%)	9 (1.9%)	16 (1.8%)
	Collagen Disorder	2 (0.4%)		2 (0.2%)
	Heart Failure	16 (3.6%)	14 (3.0%)	30 (3.3%)
	Immunosuppression	4 (0.9%)	6 (1.3%)	10 (1.1%)
	No	342 (76.3%)	362 (78.2%)	704 (77.3%)
	Pulmonary-other	15 (3.3%)	11 (2.4%)	26 (2.9%)
Non-inguinal chronic pain	No	362 (80.8%)	352 (76.0%)	714 (78.4%)
	Yes	86 (19.2%)	111 (24.0%)	197 (21.6%)

(626/911)), without non-inguinal chronic pain (78.05% (711/911)). Overall, included patients had a normal BMI (43.5% (396/911)). However, in the ultrasound group, a BMI between 25 and 29.9 kg/m2 was more frequently reported (43.0% (199/463)). Patients were mostly low-risk, with ASA grades between 1 and 2 (81.7% (744/911)) and non-smokers (56.2% (512/911)). Detailed preoperative data is shown in Table 1.

For most patients, this was the first hernia repair (78.0% (711/911)) and a family history of inguinal hernia was not present (76.4% (694/911)). At the time of admission, 68.87% (626/911) of patients had symptoms related to the hernia, 67.9% (304/448) in the physical evaluation group and 69.5% (322/463) in the ultrasound group. Additionally, 76.9% (691/911) had preoperative inguinal pain, even if not present at the time of admission, 76.6% (337/448) in the physical evaluation group and 77.1% (354/463) in the ultrasound group (table 2).

Overall, most patients had hernias with a defect larger than 1.5 cm (59.4% (541/911)). This was verified in both the physical evaluation (62.5% (280/448)) and ultrasound (56.4% (261/463)) groups. Lightweight (67.9% (534/911)) and absorbable meshes (60.8% (554/911)) were used in most surgical repairs. Most patients underwent general anesthesia (62.7% (571/911)) (Appendix 2 – Table 5) and were admitted to the hospital (49.5% (451/911)). Full intraoperative details are shown in Table 3.

There were no statistically significant differences in the patient, symptoms and hernia characteristics between the two groups. Equally, there were no statistically significant differences in intraoperative data.

Table 2: Description of patients' hernia characteristics.

		Physical evaluation (n=448)	Ultrasound (n=463)	Total (n=911)
Family History of Inguinal Hernia	No	351 (78.7%)	343 (74.2%)	694 (76.4%)
	Yes	95 (21.3%)	119 (25.8%)	214 (23.6%)
Previous Inguinal Hernia	No	347 (77.5%)	364 (78.6%)	711 (78.0%)
	Yes	101 (22.5%)	99 (21.4%)	200 (22.0%)
Preoperative Inguinal Pain	No	103 (23.4%)	105 (22.9%)	208 (23.1%)
	Yes	337 (76.6%)	354 (77.1%)	691 (76.9%)
Hernia side	Unilateral	389 (86.8%)	390 (84.2%)	779 (85.5%)
	Bilateral	46 (10.3%)	65 (14.0%)	111 (12.2%)
	(Missing)	13 (2.9%)	8 (1.7%)	21 (2.3%)
Surgical indication	Asymptomatic or minimally symptomatic	142 (31.7%)	141 (30.5%)	283 (31.1%)
	Symptomatic	304 (67.9%)	322 (69.5%)	626 (68.7%)
	(Missing)	2 (0.4%)	0 (0.0%)	2 (0.2%)

Looking at intraoperative data, Lichtenstein was the most commonly used surgical technique (50.88% (460/911). Both in the physical evaluation (38.6% (172/448)) and ultrasound groups (34.5% (158/463)), Plug and Patch was the second most common procedure. Only 4.1% (37/911) patients were treated endoscopically. A more detailed version of the surgical technique is available in Appendix 2 (Table 4).

Regarding variables that might influence the choice of surgical technique (Figure 2), there was no association with the patient's sex or hernia laterality. Ultrasound was also not associated with the choice of surgical technique (adjusted odds ratio 1.02, 0.71-1.48, p=0.901). However, previous hernia surgery and hernia size were the variables that seemed to influence the choice of surgical technique (adjusted odds ratio 2.17, 1.37-3.43, p=0.001).

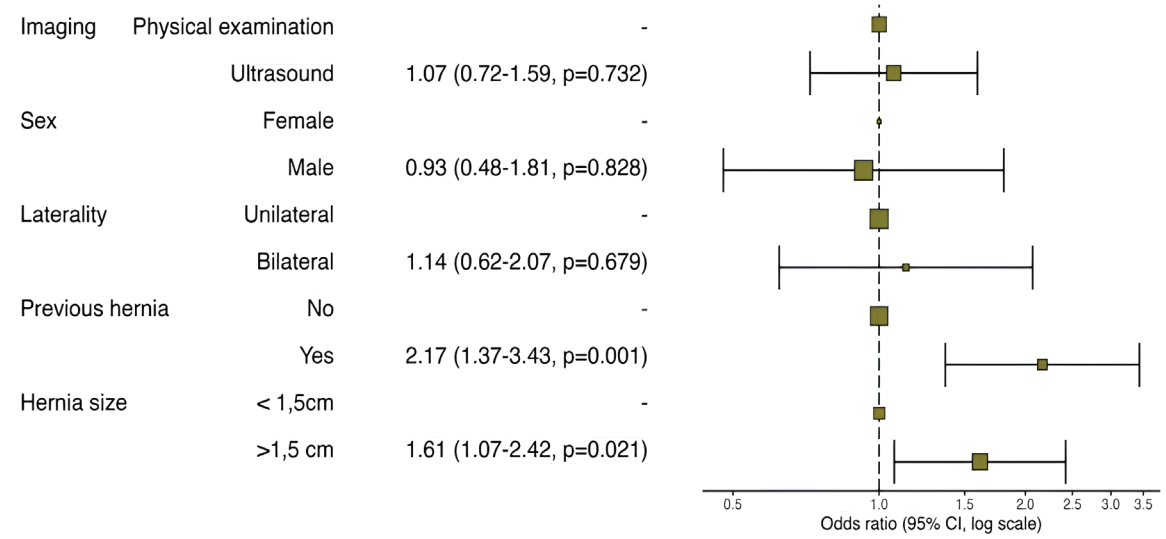

Figure 2: Intraoperative characteristics model.

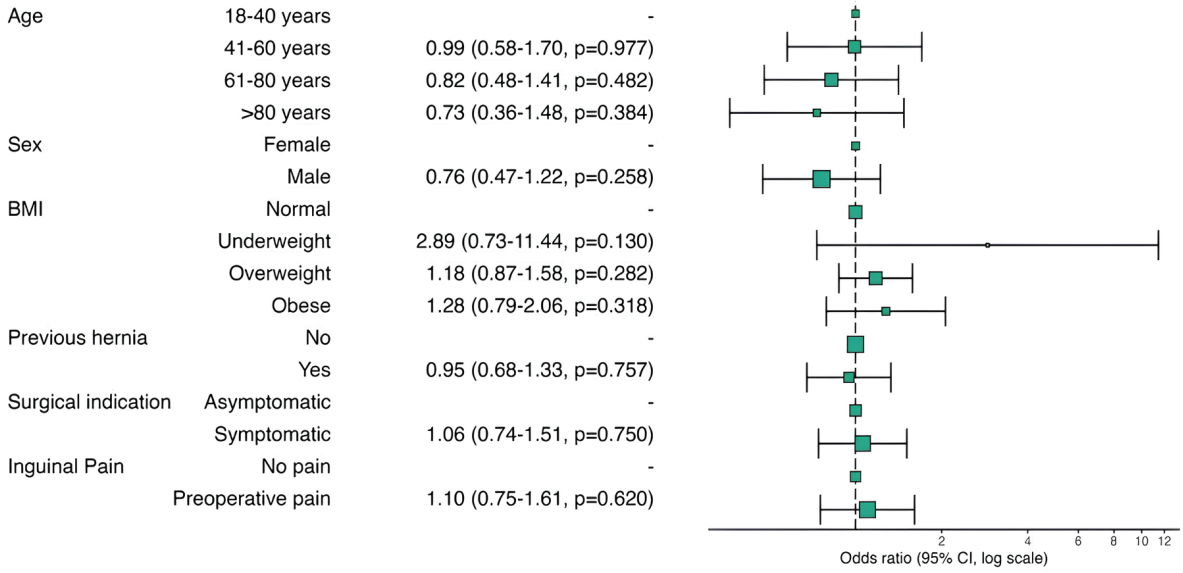

Figure 3: Patient characteristics model. "Asymptomatic" includes minimally symptomatic and asymptomatic patients.

When testing the association of patient characteristics with the use of preoperative ultrasound (Figure 3), there was no association between the patient's age, sex or BMI, and performing an ultrasound. Likewise, previous hernia repair (adjusted odds ratio 0.95, 0.68-1.33, p=0.757), surgical indication (adjusted odds ratio 1.06, 0.74-1.51, p=0.750) and inguinal pain (adjusted odds ratio 1.10, 0.75-1.61, p=0.620) showed no statistically significant association.

Discussion:

This study showed that while ultrasound is not routinely recommended for diagnosing inguinal hernia, it was used in a significant proportion of cases in Portugal without influencing the choice of surgical technique. This finding is in keeping with the literature, where the choice of surgical technique is usually related to the occurrence of a previous hernia, patient risk characteristics and available surgical expertise [6]. In the elective setting, the occurrence of a hidden contralateral hernia would be a radiological finding that could potentially influence surgical technique and favor a laparoscopic approach [5, 6]. However, in this population, only 12.2% of patients had bilateral hernias, and no association with surgical technique was found.

This study also showed that age, sex, BMI, previous hernia repair, surgical indication and inguinal pain were not associated with a higher likelihood of using ultrasound as a diagnostic tool. Additionally, the characteristics of the patient, hernia and intra-operative variables were not statistically different between patients diagnosed with ultrasound versus physical evaluation. This scarcity of differences between the two groups supports the lack of benefit in using ultrasound to diagnose inguinal hernias and does not explain its high adoption. Theoretically, it would be expected that patients diagnosed with ultrasound would be less symptomatic (and, thus, a statistically significant difference in surgical indication was anticipated) and have less preoperative inguinal pain, than patients in the physical evaluation group.

Although this study did not include patients eligible for surgery who did not undergo surgery, previous literature reports that the use of ultrasound does not have an influence on the decision to operate and has limited value in this setting [12, 13]. This highlights the urgency in reducing unnecessary tests, saving healthcare costs and resources.

The strength of this study is the realistic sample of the current clinical practice and the comprehensive view as it was a nationally distributed multicenter cohort study with 33 Portuguese hospitals. Interpreting the findings with available literature and clinical practice, it is reasonable to assume that a high degree of preoperative imaging requests were carried out before observation by a surgeon [8, 12, 13, 17, 18]. This highlights the need to broaden clinical knowledge of inguinal hernia management, but also to review the criteria for referring patients to the hospital.

The study has limitations. Patients with other diagnoses and occult hernias may have benefited from ultrasound

Table 3: Description of intraoperative data.

		Physical evaluation (n=448)	Ultrasound (n=463)	Total (n=911)
Surgical Technique	Lichtenstein	225 (50.2%)	235 (50.8%)	460 (50.5%)
	Others	221 (49.3%)	223 (48.2%)	444 (48.7%)
	(Missing)	2 (0.4%)	5 (1.1%)	7 (0.8%)
Hernia size	< 1,5cm	118 (26.3%)	144 (31.1%)	262 (28.8%)
	>1,5 cm	280 (62.5%)	261 (56.4%)	541 (59.4%)
	(Missing)	50 (11.2%)	58 (12.5%)	108 (11.9%)
Type of mesh	Heavy	132 (34.2%)	120 (30.0%)	252 (32.1%)
	Light	254 (65.8%)	280 (70.0%)	534 (67.9%)
Mesh fixation	Absorbable	261 (58.3%)	293 (63.3%)	554 (60.8%)
	Non-absorbable	186 (41.5%)	169 (36.5%)	355 (39.0%)
	(Missing)	1 (0.2%)	1 (0.2%)	2 (0.2%)
Anesthesia	General	280 (62.5%)	291 (62.9%)	571 (62.7%)
	Regional	161 (35.9%)	165 (35.6%)	326 (35.8%)
	Local	5 (1.1%)	6 (1.3%)	11 (1.2%)
	(Missing)	2 (0.4%)	1 (0.2%)	3 (0.3%)
Setting	Admitted	229 (51.1%)	222 (47.9%)	451 (49.5%)
	Day-case	203 (45.3%)	222 (47.9%)	425 (46.7%)
	(Missing)	16 (3.6%)	19 (4.1%)	35 (3.8%)

scan, although and we did not collect these data. Additionally, this analysis presents a selection bias, as all the patients who were included where referred to General Surgery consultation and submitted to elective inguinal hernia repair. Thus, patients who underwent an ultrasound with a negative result were not captured.

Knowing the training of the physician requesting the exam would have also been useful, both in terms of medical specialty (Family Medicine or General Surgery) and in terms of the level of training (intern, trainee, consultant) to consider adequate interventions. Despite not having explored this topic within the study, knowledge of pathways within the Portuguese health system raises a hypothesis: high use of ultrasound is supported by a similarly elevated refusal rate by the hospital, when Family Medicine physicians refer patients with inguinal hernia suspicion without supporting exams. Thus, it would be important to ascertain where the diagnosis was made (i.e. in primary care or hospital setting) as an ultrasound requested by a surgeon could have had a bigger impact on the treatment strategy than one requested at primary care.

Future research is needed to fully understand and address the high use of ultrasound. Furthermore, literature proves that the overuse of diagnostic ultrasound is not limited to Portugal. For example, in Canada, a retrospective analysis from Marcil et al. [12] reported that 70.6% of preoperative ultrasounds occurred before a General Surgery consultation [12]. Additionally, both international guidelines [6] and different Choosing Wisely [19] campaigns have advised against the routine use of ultrasound in inguinal hernia patients [17, 20].

Future studies should approach both primary care and hospital settings. Regarding primary care, the ability to diagnose inguinal hernia with physical evaluation should be reviewed. In the hospital setting, criteria for acceptance and/or refusal of patients for General Surgery consultations must be evaluated. Both should

be conducted in each hospital/primary care unit related to the hospital as service evaluations to map the factors that need improvement locally.

This study highlighted future points of action for policymakers, universities and specialty colleges. Knowledge of inguinal hernia diagnosis might need to be encouraged and actively taught to reduce the use of ultrasound. Although we could not identify the specific cost for ultrasound to diagnose inguinal hernia, this imaging exam is not cost-effective in this setting. To reduce its use, improving the training program for physicians to diagnose inguinal hernia more confidently with physical evaluation is urgently needed. Furthermore, a national review of the referral criteria will allow the implementation of a standardised and uniform consensus, that is adjusted to current scientific evidence, and that prevents the usage of ultrasound solely as a facilitator for hospital consultation. Ultimately, interventions must not only guarantee that primary care physicians are able to clinically diagnose inguinal hernia, but also ensure the hospitals' capacity to adequately accept referrals

This study can have a multidimensional impact that encompasses three major areas - patient, society and health services. For the patient, a diagnosis based on physical evaluation will allow them an earlier hospital referral, with the expected effect of reducing waiting times and the need for emergency surgery. For society, shorter waiting times are expected to be associated with lower work absenteeism rates, quality of life improvement and disability-adjusted life year (DALY) reduction. For the health service, and considering the limited budget, the reduction of cost and burden of unnecessary exams will allow spending on further cost-effective interventions. More than identifying a problem, we hope the results of this study allow for interventions suited to the real needs of patients.

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