The development and review of patient information leaflets for varicoceole embolisation and fluoroscopy guided joint injection examinations

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Aims and objectives

Radiology interventional procedures are continually developing, requiring associated patient information leaflets (PILs). The general notion is that PILs are an essential educational tool for patients who are eager to acquire more information regarding their personal health and procedures to make informed decisions as "without information there is no choice." [1,2,3] PILs can help to fill information gaps and provide the patient with tangible and accurate information that can be referred to at any time after consultation with the added advantage that the information can be read and processed at the patient's pace.[4,5,6] PILs also offer the potential of enhancing the patient consent process. However a question raised by many literature sources is: do patients really understand the leaflet material that is aimed at supporting the patients participation in their own healthcare?[4,7,8,9,10]

This study aimed to develop PILs for: (i) varicoceole and (ii) fluoroscopy guided joint injection (FLGJI) examinations, to serve as an educational tool for patients, aiding informed consent.

Methods and materials

Patient interviews were planned to investigate the effectiveness of proposed PILs. Main themes such as: patient understanding of information in the PIL, readability and recall of information, compliance/adherance to instructions and patient satisfaction were focussed upon. These were explored to gain more insight about the value of providing a PIL with every patient appointment (fig. 1).

Research questions

1. What are the key points which need to be included in a PIL for patients attending interventional radiology procedures - varicoceole embolisation and FLGJI?

2. Do patients understand the information in the leaflet?

3.Do the PILs support the outpatients prepare appropriately for the procedure and manage self-care as directed through the PIL?

Designing Evidence-based PILs

The leaflets produced were designed with the insight and supervision of a resident consultant radiologist who was responsible for performing the procedures, through review of PILs and literature by the researcher, as well as some input from the angiography team; and thus, evidence-based PILs were developed to provide radiological procedural information - preparation, explanation of interventional procedures and aftercare.

Readability was tested via validated readability programs and the author also compared the PILs with various texts (fig. 2,3). The interpretation can be retreived with the use of Table 1.

Radiology approved content was confirmed and this constituted the expert knowledge for the leaflet production. However, this might not satisfy the information needs of the patient[11] and so the researcher included feedback from the patient experience to improve the leaflets to support a more patient oriented outcome.

Leaflet Distribution

The process for leaflet from production to distribution is outlined in figure 4. Target Population Inclusion Criteria:

- Outpatients only
- Patients who were able to understand the written Maltese or English language

Target Population Exclusion Criteria:

- Patient who were unable to communication
- Patients who could not or did not read the leaflet.

Patient feedback sessions

Consent was sought before patients were interviewed. The interview was conducted either in Maltese or English according to the patients' choice, to facilitate their understanding and answering of questions but since this was an interview, at times the researcher could also switch languages in order to allow the best chance for the patient to fully understand what was being asked. Questions were created, aligned to sections from the leaflet to test for understanding, readability, memory and compliance. The first few patients (n=6 overall; 4 for FLGJI and 2 for varicoceole embolisation) who accepted to participate in the survey were allocated for pilot involvement, to test the research instrument's reliability and the changes suggested, at validity stage.

The information gathered by the questions in the interview schedule underpinned:

<u>For both leaflets</u>

- Demographics: to obtain a picture of the participant's sex, age and

education level.

- Confirmation that the leaflet was read.

- Preferance between language chosen was identified.

Additional questions were asked to test the readability and understanding of the leaflet and also to identify satisfaction of information provided.

Varicoceole embolisation leaflet specific questions:

- Understanding of varicoceole embolisation and from where was information obtained.

- Questions about: local anaesthesia, remaining hydrated by drinking water, if they knew who would perform the procedure, whether they knew what medicine would be injected in the joint, where all asked to test the level of understanding as well as attention after having read the leaflet.

- Participants were asked for their opinion on the leaflet and whether they felt reassured by it. Recommendations that could enhance the leaflet were requested.

- The length of the leaflet was queried and participants rated the importance of the sections.

Fluoroscopy guided joint injection leaflet specific questions:

- Some patients were returning patients so participants were asked whether they were first time patients.

- To check understanding of the leaflet; participants were asked if they knew: who would perform the procedure, what is local anaesthetic, what medicine would be injected in the joint and prompted to mention

some of the instructions listed as important to tell the staff before examination.

- The leaflet was rated by the participant for relevance of the various sections and their opinion sought for recommendations that could enhance the leaflet.

- The participants were also asked whether they felt reassured by the leaflet and the length of the leaflet was queried.

Post-procedure Telephone Interviews

Participants were contacted 7 days post-procedure to check if the leaflet matched the reality of their experience, whether they adhered to the instructions of aftercare and if they needed to call their doctor due to pain in the following days after the procedure. They were finally asked if they had suggestions for the leaflet to add value to the information in the leaflet.

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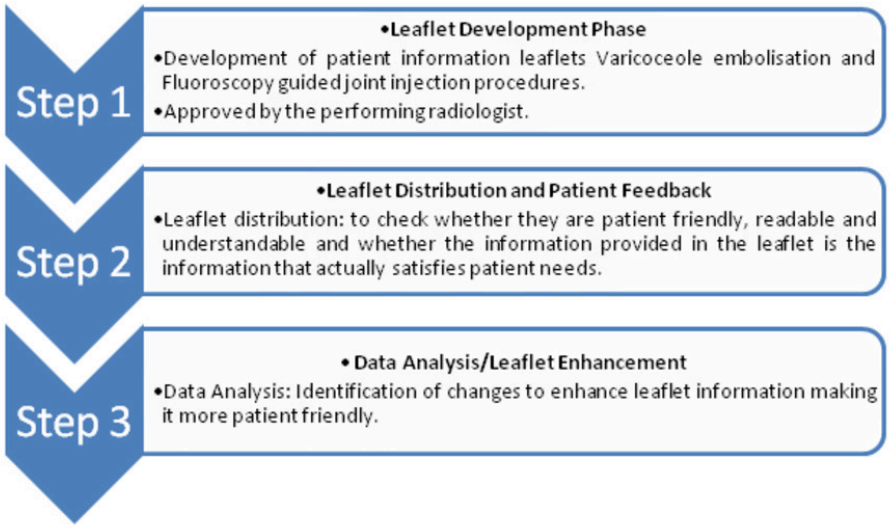

Fig. 1: Schematic flow diagram outlining the stages of the research study.

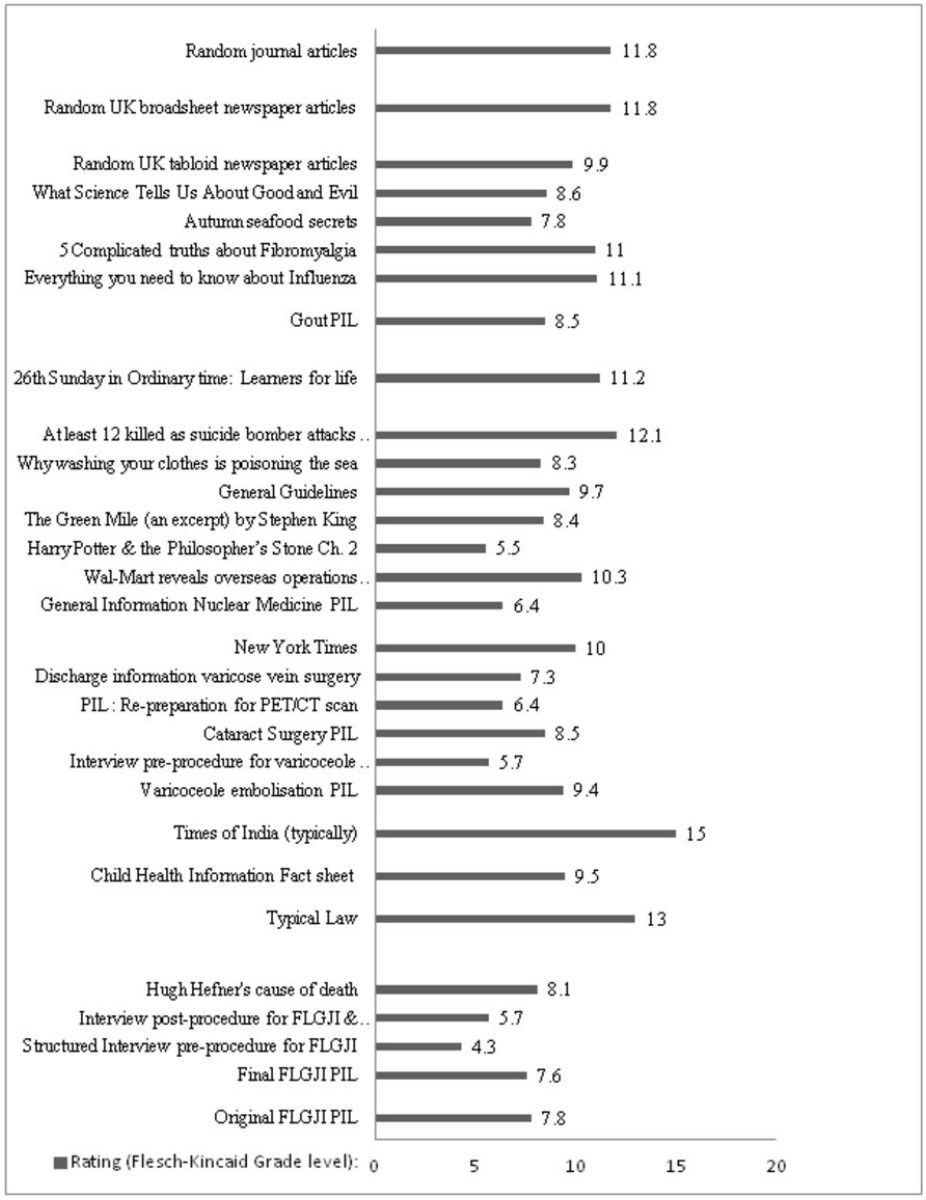

Fig. 2: Summary of the items assessed with Flesch-Kincaid Grade Level

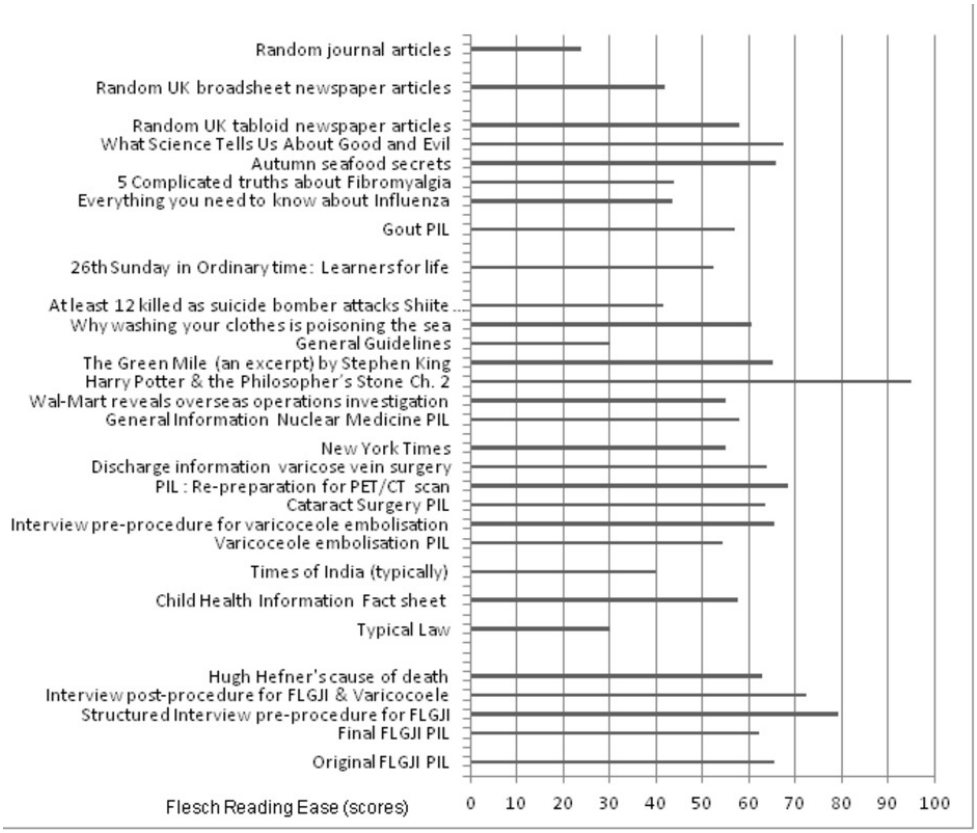

Fig. 3: Examples of items assessed using the Flesch Reading Ease method.

Flesch Kincaid Grade Levels		Flesch Ease Reading Score	
Grade	**Reading Age**	**Descriptor**	**Score**
6	11-12	Very Easy	100-90
7	12-13	Easy	89-80
8	13-14	Fairly Easy	79-70
9	14-15	Plain English	69-60
10	15-16	Fairly Difficult	59-50
11	16-17	Difficult	49-30
		Very Difficult	29-0

Table 1: A summary of readability scoring interpretation

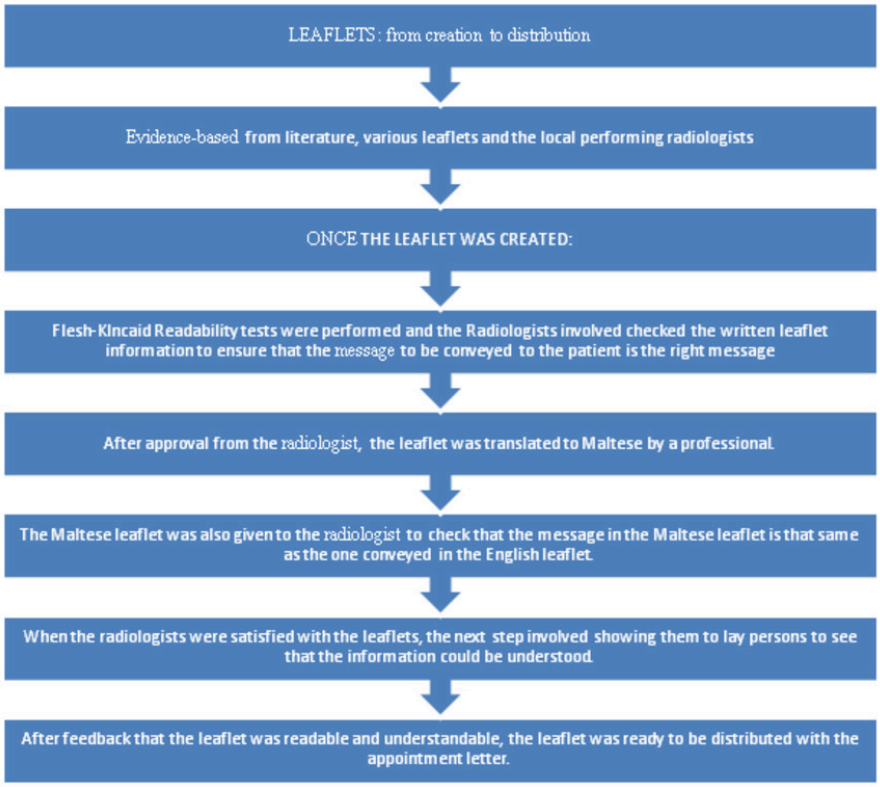

Fig. 4: Outline of the approval process for leaflet production

Results

Leaflet Readability

The results presented include scores and ratings interpreted accordingly.[12,13,14] The varicoceole embolisation leaflet scored 54.4 and is therefore rated as fairly difficult to read. It also had a rating of 9.4 meaning that the reading age is suitable for a 14-15 year old. The FLGJI leaflet achieved a score of 62.2 and is therefore of plain English standard. It also had a rating of 7.6, meaning that the reading age is suitable for a 12-13 year old.

The Participants

The total cohort of 64 participants interviewed overall for both procedures : varicoceole embolisation (n=17) males only, and fluoroscopy guided joint injection (n=47);18 (38%) males and 29 (62%) females). The ratio of male: female is comparable to that stated by Peterson's group[15] where out of 348 guided joint injections 39% where males and 61% where females.

Age distribution

Figure 5 shows frequency compared with age for the varicoceole embolisation patients. Ranging minimum to maximum ages: 18-70, mean=37.41, median 34 and mode 33. The 8 patients in the 30-35 group constituted 47% of participants showing that 30 to 35 years stand out as the ages when most varicocoele embolisation procedures are carried out at participating centre.

FLGJI patients are more common in the over 50 age range at the participating centre (age ranged: 19-81, median age = 58, mean = 55.3 and mode 34), with a percentage of nearly 66% and with a mean age of 54 years, similar for the large Peterson group trial.[15] The frequency of the participants is summarised in Figure 6.

Level of education of participants

The level of education for varicoceole embolisation patients was generally high. 70.6% of the varicocoele cohort is made up of the two higher level education categories - post-

secondary and tertiary education, whereas the remaining 29.4% is to be attributed to secondary education. The level of education for the FLGJI patients was generally lower than the varicoceole embolisation group. 34 out of a total of 47 fall in the lower two education level categories making up 72.3% of the sample population (table 2).

Education and Age Effects

Comparing age and education for the FLGJI cohort proved to be significant with (p=0.006). Above 80% of patients, who had passed the 60 years of age, had only primary education and these made up nearly 40% of the whole FLGJI sample. Interestingly, varicoceole embolisation participants who did not read the leaflet, made up 40% of those in the secondary school level category only - the lowest education category recorded for the varicoceole group.

Language preferance

Significant findings for education vs. language preference were demonstrated (p value=0.007). No participant with primary education chose to read the English leaflet, whereas 75% of the FLGJI cohort with tertiary education preferred to read the English leaflet. This highlights the importance of having PILs presented in the native language especially for the lower literacy groups.

Both varicoceole embolisation patients and FLGJI patients stated they preferred the Maltese to the English leaflet. Combing both groups of participants, 78.1% preferred Maltese and 22.9% preferred English.

Feedback of returning patients

Only the FLGJI group included returning patients (n= 22), stating that the leaflet was an improvement. Some recalled being unsure and nervous on previous visits and several patients (n=16) also claimed that they might not have taken care of their joint sufficiently after the procedure due to lack of aftercare knowledge.

Compliance and Satisfaction

From the feedback gathered while interviewing the whole cohort of patient receiving both leaflets the vast majority did understand what they needed to know and the leaflets presented had satisfactory information that when asked if the they wanted to add information or even remove, no participant felt that addition or removal of information was required. The participants were also asked about the length of the leaflet and they reported this as appropriate and not lengthy. The amount and quality of information present allowed the patient to be more participant in their own healthcare and it gave them a responsibility towards taking care of themselves because the leaflet gave them enough knowledge to enable them to be autonomous, making them aware and conscious that they were part of the process and that their participation was important for the success of their procedure. Thus knowing the basic information and how to take care of oneself made the patient aware of the possibilities and what to expect.

Two patients who stated they had joint injections, but without the aid of x-rays in the past, claimed that they would have declined the procedure if they had not read that this was x-ray guided. This indicates that the role of the PIL is to help the patient make an informed choice.

The paragraph describing drink instructions for varicocoele embolisation patients was one which created some misunderstanding as 5 patients (29.4%) claimed that they were unsure whether they could drink before the procedure. The radiologist always states that the patient needs to be hydrated and so this sentence needs to be adjusted to reflect the the radiologist's recommendation.

Patient ratings for the varicocoele embolisations leaflet themes and sub-headings

Figure 7 presents a summary of subheadings that varicoceole embolisation participants identified as very important. The findings indicate that patients did not attribute a high rank to the subject: 'knowing the length of the procedure', even though some people stated that it would be good to know the approximate time for the procedure length. The least rated was 'the location of the radiology department'. Whereas 'Knowing the performer' and 'What is a varicoceole?' were highly rated.

How did varicocoele embolisation patients rate the leaflet?

For this section the participants were presented with a likert scale with 3 choices: (1) not at all; (2) to some extent; (3) to a large extent (fig. 8). All the participants rated the leaflet as easy to read. Moreover most of the other components were also highly rated since they received over 80% except for explanation of procedure which is probably the hardest paragraph to understand as it is the most technical.

Patient ratings for the FGJI leaflet themes and sub-headings

A summary of subheadings FLGJI participants identified as very important is outlined in figure 9.

A summary of participant responses in rating the FLGJI leaflet is highlighted in figure 10. All participants found the leaflet helpful and thus this was attributed the maximum value of 100%.

Images for this section:

Level	Varicocele embolisation		FLGJI	
	Number of patients	Percentage	Number of patients	Percentage
Primary	0	0.0%	12	25.5%
Secondary	5	29.4%	22	46.8%
Post-Secondary	5	29.4%	11	23.4%
Tertiary	7	41.2%	2	4.3%

Table 2: Summary of varicocele embolisation and FLGJI participants' levels of education.

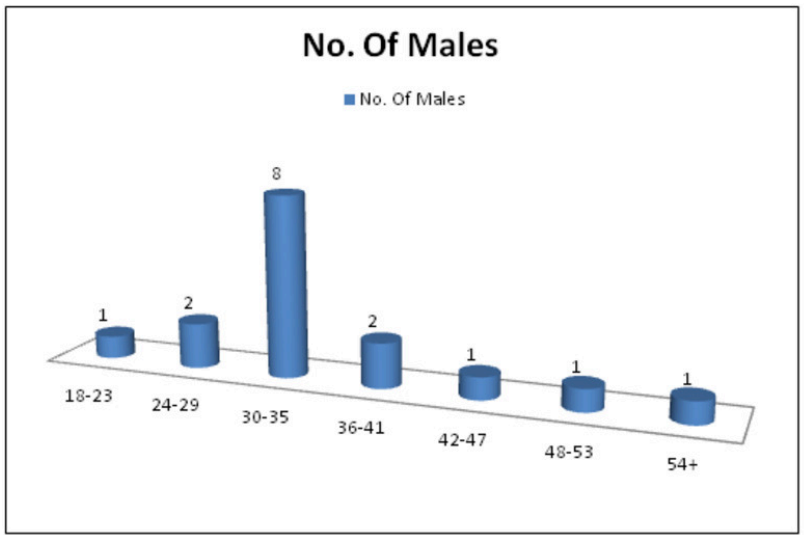

Fig. 5: Age distribution with frequency for varicoceole embolisation participants

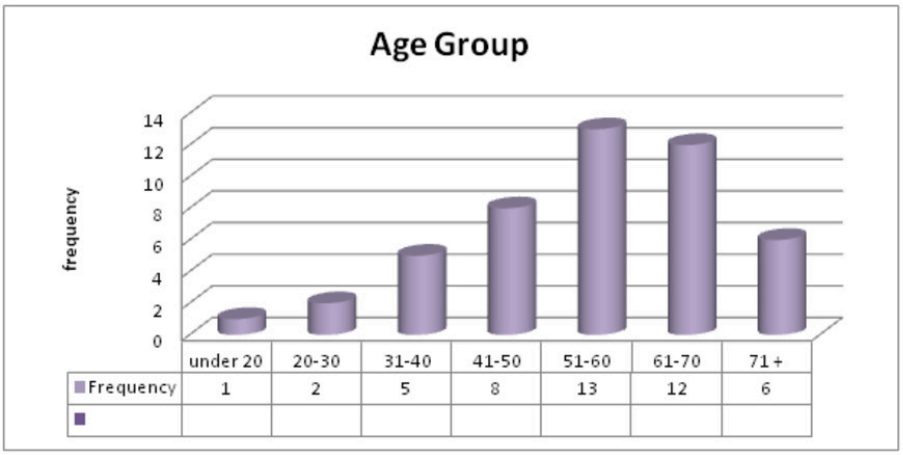

Fig. 6: Age distribution for fluoroscopy guide joint injection participants

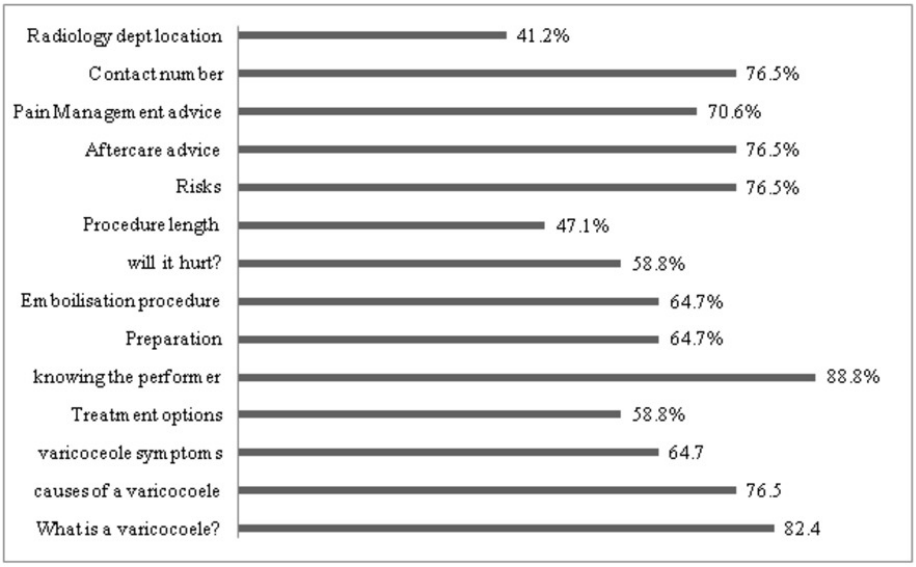

Fig. 7: subheadings varicoceole embolisation participants identified as very important

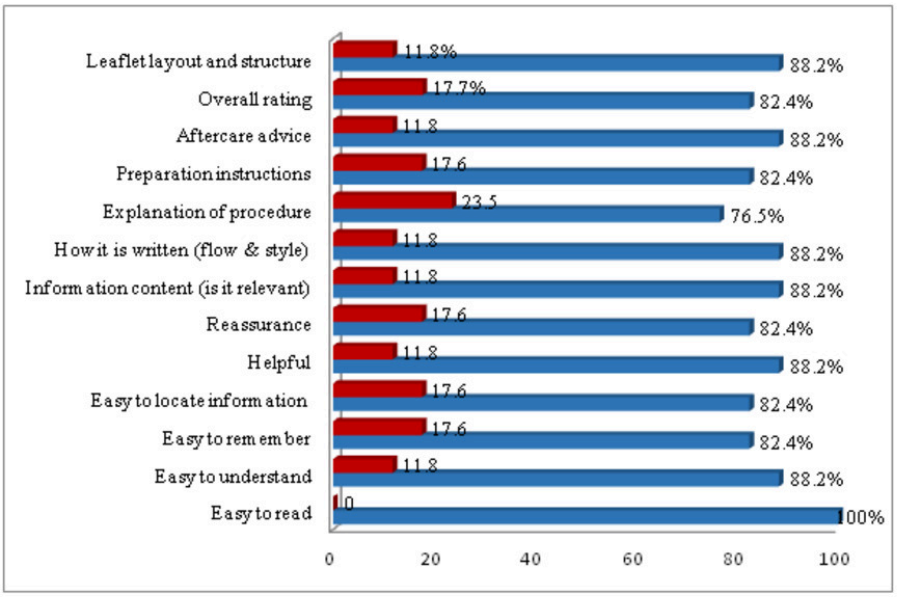

Fig. 8: Summary of participant responses in rating the varicocoele embolisation leaflet

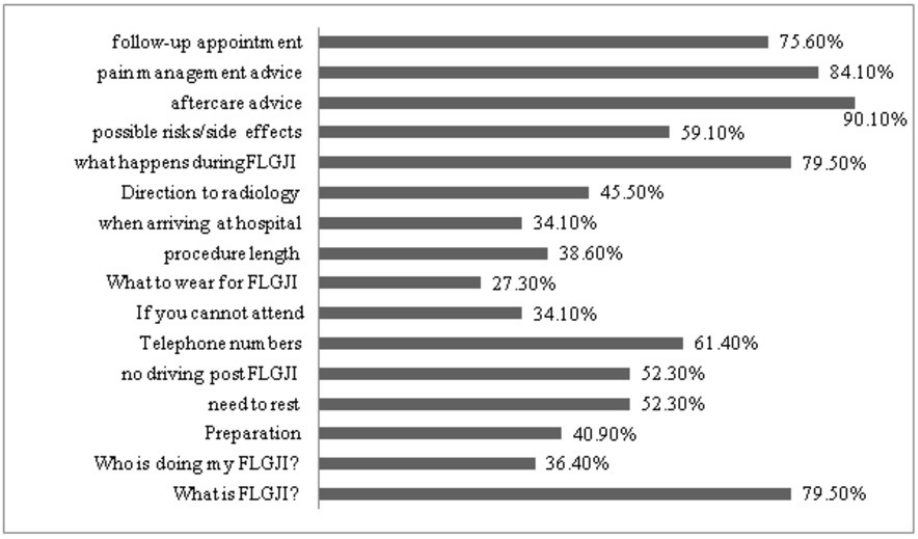

Fig. 9: Subheadings FLGJI participants identified as very important

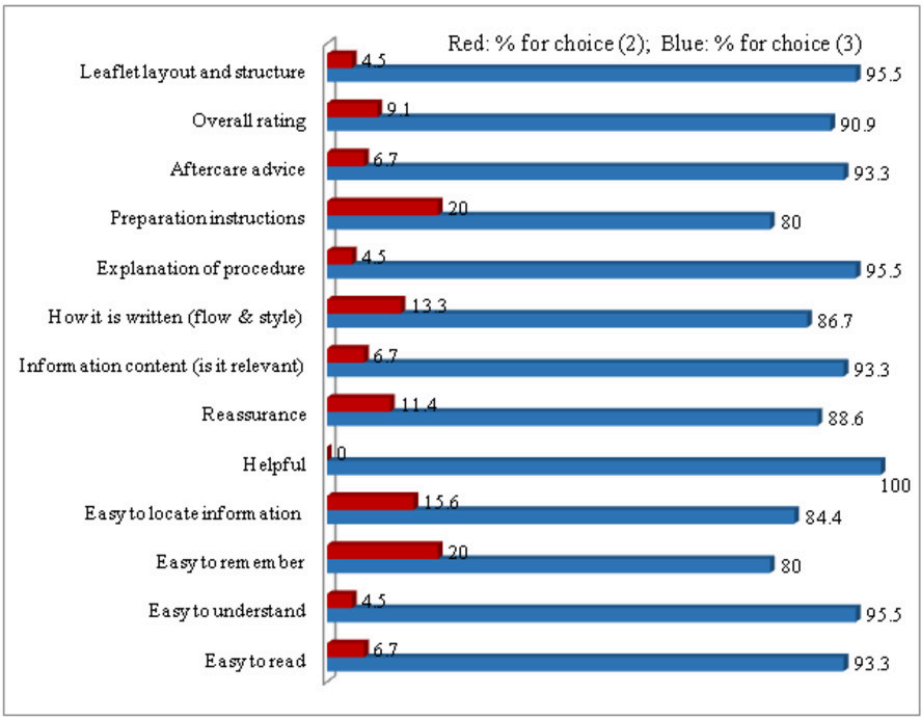

Fig. 10: Summary of participant responses in rating the FLGJI leaflet

Conclusion

Limitations

Time available to undertake this study was a limitation. However, 26 varicocoele embolisations were performed last year and 17 were completed in the 22 weeks period of data collection. Likewise for FLGJI, 39 were performed in 2016 whilst 47 patients participated in this study. The findings are relevant to the participating centre and specifically the Maltese population.

Conclusions

All the participants claimed that they had found the leaflets easy to read, understand and to adhere to instructions.

The findings demonstrated the need for all stakeholder involvement and the use of validated readability scoring/rating was deemed an appropriate element of the research methodology. The findings indicate that the patients do use the leaflets even post procedure at home.

Radiology was supportive and involved in all stages of the PIL production. The radiologists were satisfied and noted an improved confidence in patient understanding of the procedure and aftercare requirements and a positive impact on clinical service was identified.

PILs with adequate quality and information, can be a good precursor to obtain informed consent. Thus PILs should include information that is usually given by the radiologist in order to obtain informed consent.

Lack of patient information about procedures can leave some patients feeling insecure, impeding patient co-operation and clear decision making.[16,17] Moreover, PILs may provide emotional support -deemed important by the patient when assessing overall experience and quality of care.[18] Thus it is important for imaging departments to increase quality of information and upgrade PILs, to ensure that patients are satisfied with the amount and standard of health literature offered.

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